Project Management for Evidence Based Medicine: some innovative approaches to support effective healthcare projects [1]

Massimo Pirozzi and Lidia Strigari

ABSTRACT

In today's world, both the extent and the complexity of healthcare projects need special approaches to reach efficacy and efficiency respecting ethical and other constraints, preserving the care to the person by achieving the satisfaction of stakeholders, and minimizing negative risks. Evidence Based Medicine (EBM) takes into account the above factors by integrating best scientific evidence with both clinical expertise and patient values and expectations, while Project Management discipline can effectively support EBM in facing complexity. This paper introduces briefly today's complexity scenario in healthcare, gives a synthetic overview on Evidence Based Medicine, shows the utility of project management in supporting effective EBM projects by facing complexity with efficacy and efficiency, and proposes also an innovative stakeholder-centered project management approach, called Project Management X.0, and an innovative patient-centered model for Evidence Based Medicine projects, called EBM X.0, which, via their integration, may increase healthcare projects' success rates and delivered value by taking advantage of Web 1.0/2.0/3.0/4.0 technologies in order to empower, and to speed up, decision support in both project management, and project delivery, processes.

COMPLEXITY FACTORS IN TODAY'S HEALTHCARE SYSTEM

E-health is the complex of network human and technology resources, solutions, and information technologies applied to health and healthcare, and complexity theory and concepts may help to explain successes, partial successes and failures in technology-supported innovation programmes in health and social care (Greenhalgh, et al. 2018).

The condition of disease is intrinsically complex because it is poorly characterized, poorly understood, unpredictable in its natural history or associated with multiple comorbidities or socio-cultural concerns (such as poverty, poor health literacy, or beliefs or traditions). Cancer, for instance, represents one of the most complex issues to approach precisely, because it is not a stable object, but it evolves over time as a function of latent or silent parameters, which change the probability of success of any approach that alters the probability of early detecting or eradicating it. In addition, several parameters that characterize the disease are variable over time being related to the dynamism of the tumor and its interactions with the surrounding environment. Consequently, the same therapy is not equally effective between two similar subjects.

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The introduction of novel technology may bring, of course, bring important benefits, but, at the same time, may create additional complexity because of its interaction with multiple components. In particular, complexity is relevant when new technology conflicts with established technologies and when it is necessary to work to build a shared vision, engage staff, implement new practices, monitor impact, and support ongoing adaptation. In other cases, innovation (e.g. introducing artificial intelligence techniques) not only requires staff to take on new roles, but also puts staff under pressure, threatens their professional identity, values or field of practice, or even poses a risk of job loss.

In patient experience of chronic illness, the healthcare networks work aimed at managing symptoms, and at retarding - and sometimes preventing - disease progression (May, et al. 2014). In the face of these challenges, we need to better understand patients' needs and expectations to optimize healthcare resources, and this introduces additional complexity. A further complexity factor is when the supply-side value proposition is based on an underdeveloped, implausible or risky business case (thus, it is unlikely to attract investment), or the demand-side value proposition suggests that (from the patient's point of view) the technology may be undesirable, unsafe, ineffective or inaccessible. The adopting system is complex because it requires patients to undertake complex tasks such as initiating changes in therapy or making judgments about what an emergency is; or because it presupposes a capillary network available and able to coordinate with the inputs received. An example of complex adopting system is represented by the Covid-19 emergency that we are experiencing in these days.

EVIDENCE BASED MEDICINE

In healthcare, the evidences, which are objective, are foundational to support both clinical practices and scientific research in facing and solving complexity, and in minimizing related risks. Indeed, several practices that are not evidence-based may rely on tradition, intuition, or other unproven methods, and, therefore, may give unreliable and/or uncertain and/or unrepeatable results. An Evidence Based Medicine (EBM) practice is any practice or scientific research that relies on scientific evidence for guidance and decision-making in an attempt to integrate (Fig.1) the experience of the clinician, the patient' values and the best available scientific information (Brownson, et al. 2003; Sackett, et al. 1996).

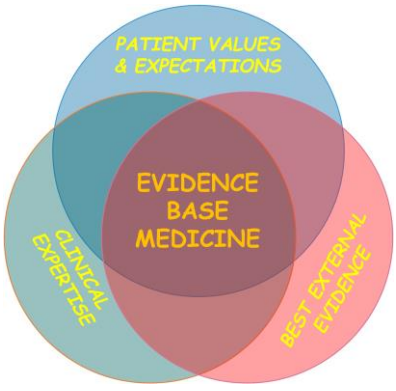

Fig.1 – Evidence Based Medicine Triad

Recently the support of IT tools contributed to the developing of communication systems between specialized personnel/doctor and patient – but also between the scientific community and the single doctor – through multiple electronic databases including a million citations in biomedicine, the life sciences, nursing, and allied health (e.g. PubMed, Scopus, EMBASE, Google Scholar etc.).

Certainly, the number of device/methods/tools has grown in recent years because we can integrate clinical and diagnostic information based on radiological or nuclear medical imaging with the information derived from the molecular/genomic or metabolic signature. These data have the characteristics of Big Data (e.g. volume: terabytes to exabytes of exiting data to process; velocity: streaming data from millisecond to days/months/years; variety: mix of structured and unstructured data as free text, multimedia; and veracity: uncertainties due to data inconsistency & incompleteness, ambiguities, latency, deception, model approximation) and may represent a barrier for the rapid learning system, for example in the case of cancer care (Abernethy et al., 2010).

What is now consolidated is that human cognitive capacity can analyze only a small number of data, therefore the management of information on the big data scale is impossible. Consequently, the process of systematic research, evaluation and use of contemporary research results as a basis for clinical decisions is not only a desirable but indispensable tool. The Five Steps of Evidence Based Medicine (Fig.2) are based on formulating clinical questions, researching, evaluating, applying evidence, monitoring one's performance. These steps of EBM apply to all phases of possible clinical trials, i.e. from preclinical studies (no humans, *in vitro* and *in vivo* only), to Phase 0 (optional first-in-human trials), to Phase 1 (first-in-person trials, screening for safety), to Phase 2 (small groups, looking for preliminary efficacy), to Phase 3 (large groups, final confirmation of safety and efficacy), and to Phase 4 (surveillance to delineate risks, benefits, and optimal use), and are repeated at each phase. The five-steps of EBM have evidently several commonalities with an adaptive/iterative project management approach.

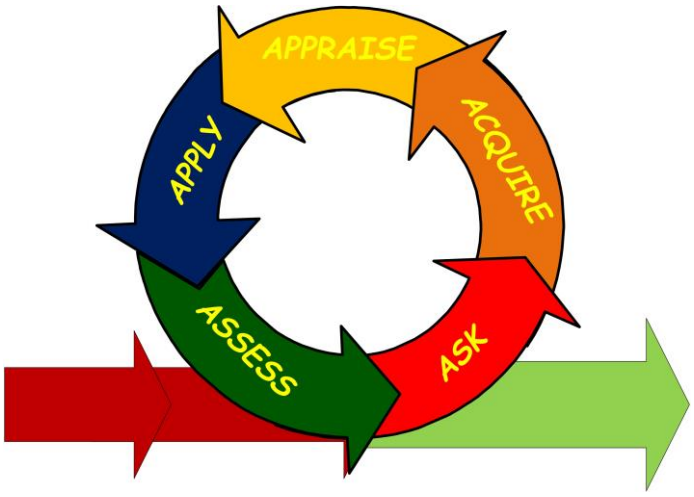

Fig.2 – Evidence Based Medicine Five-Steps

THE UTILITY OF PROJECT MANAGEMENT IN EVIDENCE BASED MEDICINE

If we want to summarize the utility of project management in a slogan, we might say "facing complexity with efficacy and efficiency". Indeed, the universal approach of the discipline combines the efficiency-oriented rigor, which is achievable through available methods, tools, and techniques by respecting constraints and by applying project management practices with the efficacy-oriented flexibility – that is achievable through the competences of the project team – of integrating project management processes, which are universally applicable, with those specific processes that are finalized to project implementation.

In fact, project management proves its utility in facing complexity, by breaking down the project into work packages of lower complexity and smaller size and by, then, integrating their outcomes, and also in implementing organizational efficiency, because project ad-hoc organizational structure enables, due also to the empowerment of all team members at an individual level, a shared, transparent, redundancies-free, professional approach. This specific approach enables operational efficiency, due to a definite, coordinated and controlled teaming, and also to realize efficacy, through continuous targeting the achievements of both project objectives, and of project stakeholder satisfaction, which are the critical success factors of each project. In addition, a risk-based thinking approach helps to take into account properly diverse, both positive and negative, contingencies.

Healthcare projects include a large variety of projects, which may be very different in typology, in size, and in complexity. Indeed, they range from the design and the realization of dedicated infrastructures to the setup of specific services, from basic to translational research, from the design and the production of specific equipment and tools to the large-scale production of medicines, of vaccines and of basic equipment and tools, from the setup of healthcare systems dedicated to the community to individual diagnosis and therapies, and so on. However, all healthcare projects share some peculiar characteristics: in fact, since focus is always on human life, aspects like the management of risks, the constraints due to ethics, the availability of lessons learned, and the attention to stakeholder satisfaction, take on an extreme importance.

For what concerns complexity, health projects can be differentiated in routine operations, in complicated projects, in complex projects, and in critical/chaotic projects; since complexity is definitively a basic driver, going deep in above levels of complexity becomes important to address the most effective support that may be given in terms of project management approach. A model which can be very helpful to face complexity, by supporting effective decision-making processes, is the well-known Cynefin® Framework, which have been created, and developed, starting from early 2000s (Snowden, 2020). Cynefin® Framework is properly a Sense-Making Model based on observation, in which "data precede model", rather than a theoretical Categorization Model, in which "model precedes data": it individuates four domains which are characterized by different levels of complexity, i.e. Simple, Complicated, Complex, and Chaotic. If we apply the Cynefin® Framework to the projects (Pirozzi, 2019), we observe that, while operations are part of

simple domain and, respectively, crisis of chaotic domain, projects may be part either of the complicated or of the complex domain (Fig.3).

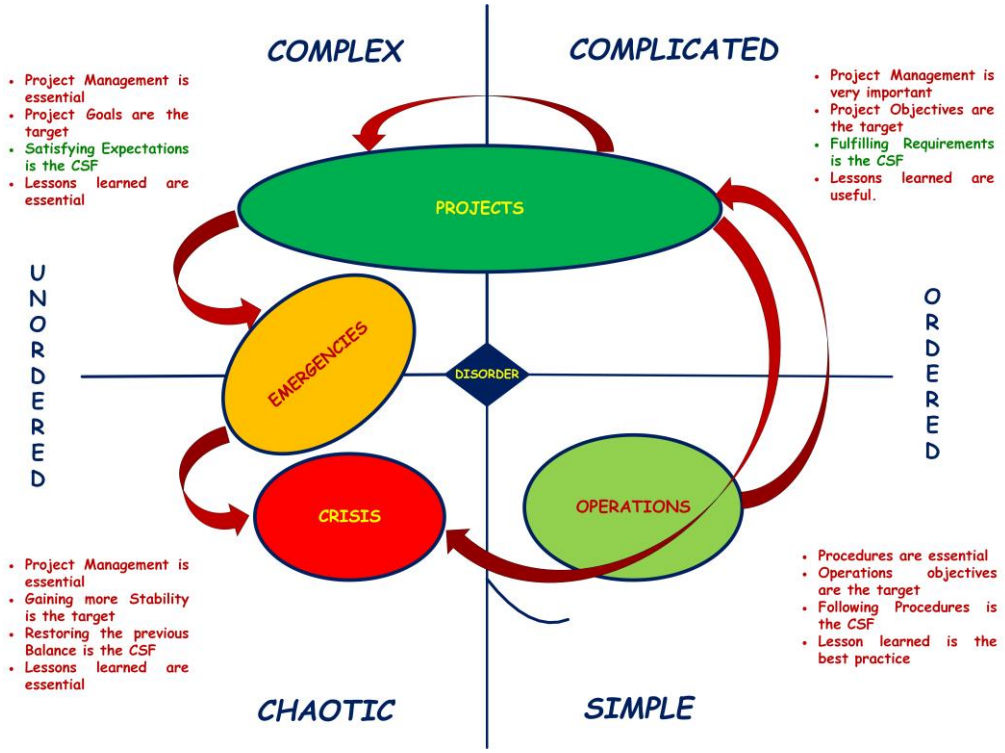

Fig.3 –Project Complexity Level in Cynefin® Framework (Pirozzi, 2019)

In complicated projects, the value generation is a consequence of achieving the target of project objectives, the discipline of project management is very important and/or essential, and fulfilling the project requirements is the critical success factor; lessons learned about good practices are very useful. In complex projects, but also in a part of "manageable" emergencies, which include those events that are substantially unpredictable, but where it is possible to plan adequate responses, and/or to manage properly the relevant risks, the value generation is a consequence of achieving the target of project goals, the discipline of project management is essential, and satisfying the stakeholder expectations is the critical success factor; lessons learned are in these cases essential to find out a proper emergent practice.

It is remarkable to notice that there is a direct, full evidence-based correspondence between above project complexity categorization and healthcare projects. In fact, in routine healthcare operations evidences are available, and, then, following appropriately the procedures is the key success factor; the most appropriate action path is sense – categorize – respond, and project management may be useful in a "managing by projects" approach, in order to gain a better efficiency. In healthcare complicated projects – e.g. in the design and realization of infrastructures and/or of equipment and/or tools – evidences are generally available, but not evident, and experts (including project

managers) are needed to collect them and to bring them out; the most appropriate action path is sense – analyze – respond, the fulfillment of requirements is the critical success factor, lessons learned about good practices are very useful, and project management discipline is very important. In complex healthcare projects – e.g. in the setup of healthcare services and in Evidence Based Medicine – evidences emerge retrospectively only, therefore the most appropriate action path is probe – sense – respond, and collecting evidences/ lessons learned is a fundamental part of the deliverables; the discipline of project management is essential, satisfying both the project requirements and the stakeholder expectations is the critical success factor, and lessons learned/evidences are essential to find out a proper emergent practice.

Definitely, Evidence Based Medicine are complex projects that have peculiar characteristics:

- ✓ they reduce threats and uncertainties by concentrating on objective and validated information;
- ✓ their triad best scientific evidence/clinical expertise/patient values and expectations requires specific focuses on lessons learned, on competences, and on available resources;
- ✓ they are stakeholder- centered because their target is satisfying both stakeholder requirements and expectations (Pirozzi, 2019), and, therefore, patients' perceived value gives a fundamental contribute to delivered value (Fig.4);
- ✓ they are multiphase, adaptive/incremental/iterative.

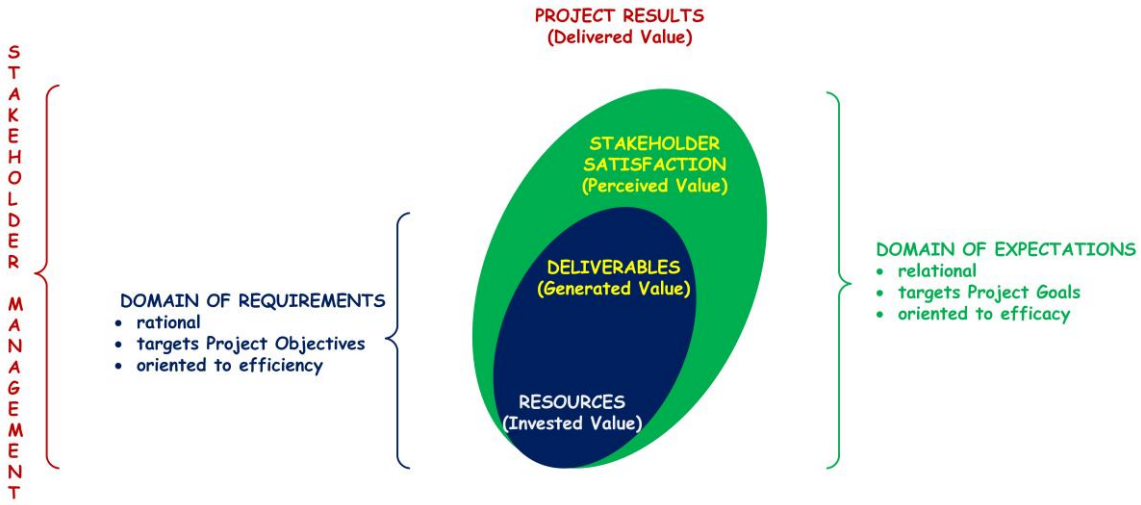

Fig.4 – The Stakeholder Perspective (Pirozzi, 2019)

Even though the benefits contributed by project management discipline are, in all cases, evident (Project Management Institute, 2018), healthcare organizations both are among the lowest performers in project management, and have shown the least amount of improvement in the higher levels of project management maturity (Pmsolutions, 2015).

However, project management is fully and effectively applicable to a large variety of healthcare projects (Schwalbe and Furlong, 2017), as well as the diverse project management approaches – i.e. predictive, adaptive/agile, and hybrid – may be effectively tailored to different applications.

A hybrid approach is here proposed for Evidence Based Medicine Project Management, because, in this way, the multiphase structure of project management processes perfectly matches with the iterative structure of Evidence Based Medicine processes. For instance, hybrid project management, in EBM projects, may integrate effectively a predictive approach for the initial planning and the final closing phases with an adaptive approach relevant to the different iterative five-step phases (Fig.5). In all cases, project managers and projects teams can deliberately and effectively tailor to EBM projects classic PM process groups initiating/ planning/ executing (implementing)/ (monitor and) controlling/ closing (Project Management Institute, 1996 and 2017, and International Organization for Standardization, 2012). In general, in a probable near future, additional focus will be made on tailoring, which is also supposed to be one of the basic delivery principles (Project Management Institute, 2020), and which is supposed to be driven by both integrated project management practices and management practices for a project (International Organization for Standardization, 2020).

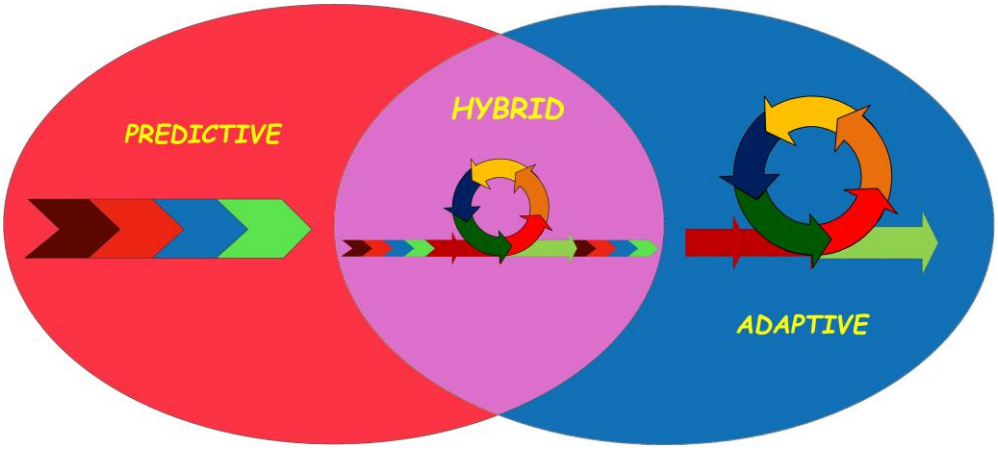

Fig.5 – Predictive, Adaptive, and Hybrid Project Management Approaches (examples)

Since all EBM projects are complex, the project success is based on the stakeholder satisfaction of their both requirements and expectations, and, therefore, managing properly the perceived value becomes mandatory in order to ensure a proper delivered value. However, successful management of the EBM project value requires adequate metrics and measures, which can be used also during project life cycle, and not only after project completion: proper Key Performance Indicators are then needed.

In general (Pirozzi, 2019), project management KPIs are especially useful to enhance project control, and to maintain and/or modify the proper route towards deliveries that fulfill stakeholder requirements: they are very helpful both in complicated and in complex projects. On the other side, economic KPIs are especially useful to improve relations with

top management and investors, and to maintain and/or modify the proper route towards the satisfaction of their economic and financial expectations: their use is basic in complex projects. Ultimately, healthcare KPIs are either common, or specific, for each typology of projects: they are especially useful to improve relations with customers and users, and to maintain and/or modify the proper route towards the satisfaction of their expectations; their use is foundational in complex projects.

For instance, examples of KPIs in healthcare projects include average hospital stay, bed occupancy rate, medical equipment utilization, patient drug cost per stay, treatment costs, patient room turnover rate, patient follow-up rate, hospital readmission rates, patient wait time, patient satisfaction, staff-to-patient ratio, canceled/missed appointments, keep track of patients' appointments, patient safety, Emergency Room wait time, and costs by payer.

In EBM projects, there are important KPIs, as functional and/or quantitative measures, and the relevant percentages of completion/deviation from budget/schedule, which are specific for each typology of projects. However, the EBM project value KPIs that are common to different project typologies are of primary importance, since they include measures and percentages of stakeholder satisfaction (in terms of both requirements and expectations), measures and percentages of stakeholder positive engagement, measures of perceived value, as perceived clinical value, social value, and personal value, perceived quality, reputation, environment climate, innovation, sustainability. Ultimately, among those EBM project value KPIs that are common to the project typologies, we can consider of top importance the KPIs that are relevant to the quantitative and qualitative measures of the evidences; nowadays, available web X.0 (i.e. 1.0, 2.0, 3.0, and 4.0) technologies can greatly enhance project management in supporting the collection and validation of qualified evidences, and their integration with clinical expertise and patient values and expectations.

INTEGRATING PROJECT MANAGEMENT X.0 APPROACH AND EBM X.0 MODEL

«We all live in a world of Project Management 2.0» (Kerzner, 2015). Indeed, interactive Web 2.0 makes powerful tools available to the community, and, in the project management domain, there is also the possibility for differently located, and even virtual, project teams, of cooperating effectively via distributed collaboration. In fact, Project Management 2.0 (Kerzner, 2015) addresses a 2.0 domain of complex projects, in which the stakeholders may be very numerous, and/or distributed, and/or with diversified interests and/or continuously interacting, where competing constraints as the value, the reputation and the quality, not only must be added to the constraints as time, cost, and risks, but become dominant, too, and whose requirements, generally, are not well defined, but are flexible and evolutionary. Ultimately, Project Management 2.0 is an evolution of Project Management 1.0 (Kerzner, 2015), which is business value-driven, which is client-centered and flexible, and which has at its disposal powerful web-based project management tools, to be used to enable the distributed collaboration, also with respect to virtual and/or not co-located teams.

It is very important to notice that, since Project Management 2.0 is focused on value delivery, it can be applied not only to operational projects, but to strategic projects too, and this characteristic someway has opened the way to a certain proposal of Project Management 3.0. In fact, a definition of Project Management 3.0 is «Project Management 3.0 is business-driven project management using value creation with a heavy focus on building a portfolio of projects» (Kerzner, 2019).

We define Project Management X.0 (Pirozzi, 2019) a stakeholder-centered evolution of Project Management 2.0 and 3.0 perspectives, which, in a near and/or medium term future, will be applicable to both project and portfolio management, and which (Fig.6):

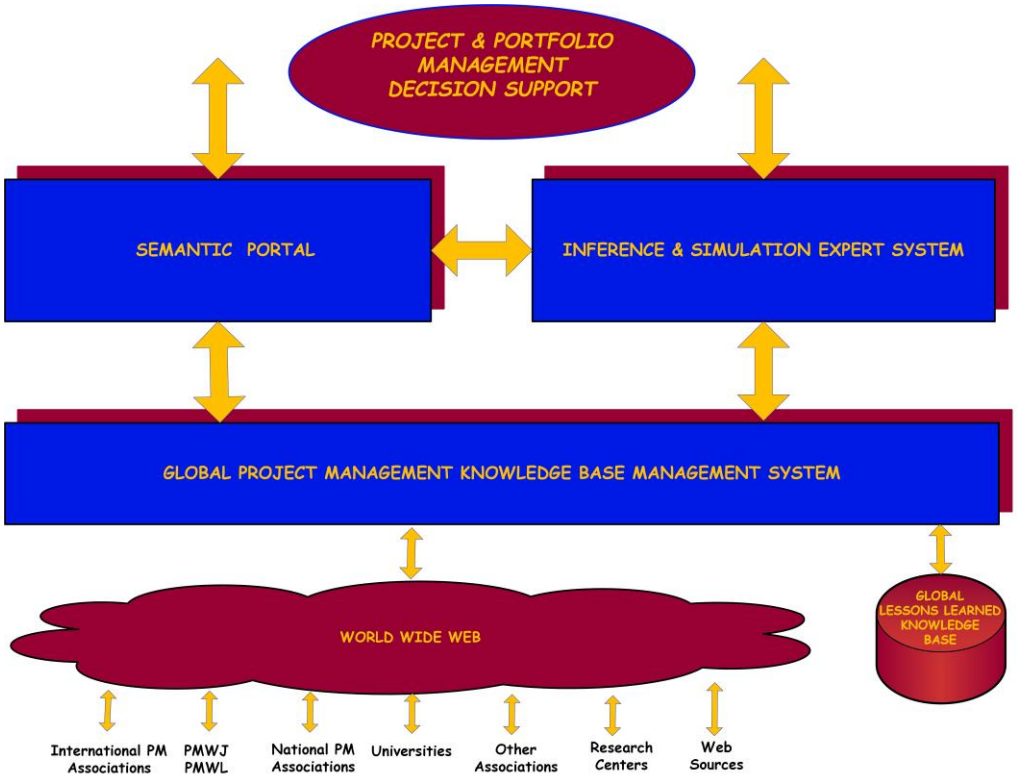

Fig. 6 – Project Management X.0 (Pirozzi, 2019)

- will import from Web 3.0 technologies and developments in terms of Web Data and of Semantic Web, in order both to make available a Global Project Management Knowledge Base of Lessons Learned, and to harmonize different languages of very diverse stakeholder communities. Indeed, the integration and the availability of Project Management Knowledge Bases from global and specific high-quality sources, including, for instance, PM World Journal and PM World Library, International PM Associations as PMI and IPMA, National PM Associations as the British APM, the Australian AIPM, the Italian ISIPM, etc., Universities, Research Centers, Associations that represent diverse

industrial/trade/sectors, other web sources, and so forth, could hugely enhance awareness, knowledge, and cooperation in project management community;

- will import from diverse dimensions of Web 4.0 those technologies and developments in terms of Big Data, Artificial Intelligence, Internet of Things, and so on, which can allow not only an enhanced, effective access to large amount of data from almost everywhere and from a variety of devices, but also the use of powerful inference and simulation expert systems to greatly increase efficacy in decision making support, so strengthening effectiveness and efficiency in both creation of business/social value and risk management.

Project Management X.0, therefore, may be a powerful web-based decision support in project management processes, because it can greatly increase the knowledge base of lessons learned – that evolve by going beyond the internal organizational domain up to ranging to a global network domain –, which can be integrated and related at different levels to support – rapid! – decisions. Indeed, decision is a crucial process in investment lifecycle, in product/service/infrastructure lifecycle, and, of course, in project lifecycle. Decisions are required both in project management daily operations – e.g. in managing relationships with stakeholders – and, in a more systematic approach, in project management event-based operations that are present in quite all project practices and process groups; most evident decision-making points in predictive project management may be are those that are present in initiating and in planning processes, those that are related to the analysis of the current situation and/or of the occurred deviations from baseline and/or of the risks, those that are related to corrective actions and/or modifications and/or changes to be made. In addition, other important decision making points that characterize specifically hybrid and adaptive approaches may be related, for example, to the decisions of proceeding with a further iteration process, of addressing a further iteration process properly, or, on the other side, of considering the phase or the project as completed, so proceeding to its closure.

The potential benefits of applying a Project Management X.0 approach to Evidence Based Medicine projects are clear, because these types of projects are based on lessons learned/ evidences, and so, as we have just seen, they can beneficiate of the enhancement of lessons learned/ evidences acquisition, correlation, and integration. Additional advantages in terms of efficacy and efficiency can be obtained if we apply also to EBM project processes an EBM X.0 approach (Fig.7), which is based on a Web X.0 support too, and which, on one side, can correspond very well with PM X.0 processes, while, on the other, may be perfectly integrated with them. Specifically, for example, Web 1.0 technologies may support EBM in terms of information (texts, images, data, signals), Web 2.0 technologies in terms of interactivity, distributed collaboration, and web portal, Web 3.0 technologies in terms of web data, semantic web, and evidence knowledge base, Web 4.0 technologies in terms of Artificial Intelligence, expert system, Big Data, Internet of Things, inferencing and simulation.

Fig.7 – Web X.0 Perspective in Evidence Based Medicine

EBM X.0 Model (Fig. 8) particularly empowers acquirement step. A variety of clinical and patient information – probably not anymore associated to people identities for privacy reasons – from diverse branches of the healthcare organization(s) (e.g. patient records, scans, scintigraphies, genetics, ecographies, labs data, etc.) and from external web-based sources (e.g. publications, researches, etc.) are integrated in an Evidence Knowledge Base, in which ontologies-based semantic aggregation and reconciliation, verification and validation etc. take place. Above Evidence Knowledge Base exchanges information with an Evidence Semantic Portal and an Artificial Intelligence and Inferencing Expert System, which, on turn, interact each other. Evidence Semantic Portal is dedicated to navigation, search and extraction, markers evaluation, information sharing, while Artificial Intelligence and Inferencing Expert System mainly takes care of multilevel modeling (levels, images, flows), of bioimaging and biosignaling informatics, and of inference engines (statistical, Bayesian, fuzzy logic); both of them contribute to the appraisal step and, therefore, to application and assessment steps, and, if this is the case, to a subsequent asking step, so starting a new iteration.

In conclusion, a stakeholder-centered project management approach that uses KPIs may help to face the complexity of EBM projects with efficacy and efficiency, while the integration between the stakeholder-centered, web-based, approach Project Management X.0, and the patient-centered, web-based, model EBM X.0, may increase projects' success rates and delivered value by taking advantage of Web 1.0/2.0/3.0/4.0 technologies in order to empower, and to speed up, decision support in both project management practices and project delivery processes.

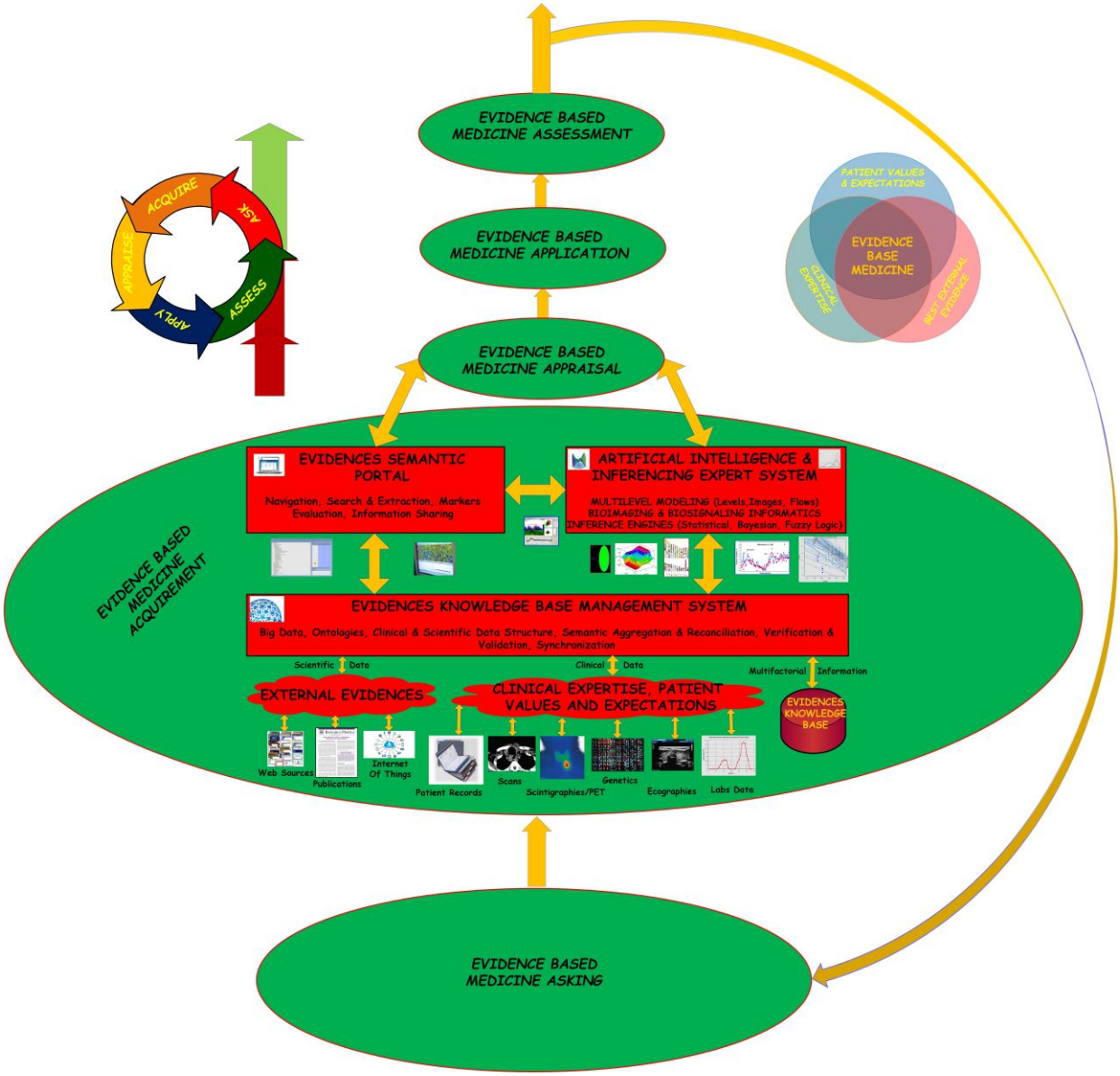

Fig. 8 – Evidence Based Medicine X.0 Model

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Massimo Pirozzi, MSc cum laude, Electronic Engineering, University of Rome "La Sapienza", Principal Consultant, Project Manager, and Educator. He is a Member of the Executive Board and of the Scientific Committee, and an Accredited Master Teacher, of the Istituto Italiano di Project Management (Italian Institute of Project Management). He is certified as a Professional Project Manager, as an Information Security Management Systems Lead Auditor, and as an International Mediator. He is a Researcher, a Lecturer, and an Author about Stakeholder Management, Relationship Management, and Complex Projects Management, and his papers have been published in U.S.A., in Italy, and also in Russia; in particular, he is the Author of the innovative Book "*The Stakeholder Perspective: Relationship Management to enhance Project value and Success*", CRC Press, Taylor & Francis Group, Boca Raton (FL), U.S.A., October 2019. Due to the acknowledgement of his comments on stakeholder-related issues contained in Exposure Draft of The Standard for Project Management - 7th Edition, he will be also included in the list of *Contributors and Reviewers of The PMBOK® Guide - Seventh Edition*.

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Lidia Strigari is a well-recognized clinical researcher both at national and international levels, who focused her research interests on the fields of dosimetry, radiobiological models, different radiation treatment modalities, systemic therapy and diagnostic and she. She has been also involved in phase II and phase III clinical trials on moderate hypofractionation and dose escalation for prostate and breast cancer, thus balancing and complementing her knowledge with translational research issues. Publication record – with more than 170 articles published in indexed/peer-reviewed journals (h-index=25), several book chapters – and two patents (PCT/IT2014/000147, PCT/IB2016/052002) evidence her strong expertise in all these fields of research. She is and has been a principal investigator of several international and national projects, in collaboration with important Research Centers and Institutions, receiving and managing founds by Ministry of Health, AIRC, INAIL, Lazio Region, and NATO. She has been a member of "dosimetry committee" of European Association of Nuclear Medicine Dosimetry Committee, as an expert of radiobiology. She is a member of "EANM Radiobiology Working Group" and of International Commission on Radiation Units & Measurements (ICRU) Report Committee 31 - "Treatment Planning for Radiopharmaceutical Therapy".

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