ETM

ENGINEERING & TECHNOLOGY MANAGEMENT

System engineering in health care system:

A case study for self-monitoring technology

Course Title: Science & Technology Policy

Course Number: ETM 575/675

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Term: Winter

Year: 2017

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1. Abstract (Objective)

This paper aims to spot areas that policy should focus on in order to have a healthy ecosystem for the current and potential diabetic people in U.S by implementing a roadmapping analysis to 15 years from now. It examines several drivers involved in societal issue that technological capability can solve. Also, system engineering view used to cover several interconnected aspect to this social problem. The paper uses a self-monitoring technology as a case study to examine this issues.

2. Introduction

System engineering is interdisciplinary field who creates and executes process across a particular ecosystem to assure that the requirements are met through high quality, efficient, effective, and low cost methods [1]. System engineering has proven its capability to deliver high quality and cost-effective results in complex environment. However, one of most complex system is health care sector. Health care system has high interconnectedness and regulated. Applying system engineering principles is beneficial to deal with such a complicated system. Applying system engineering principles in health care system by using a self-monitoring technology as a case study is covered. Integrating self-monitoring technology or more advanced technology into the healthcare ecosystem can be problematic. Therefore, to gain robust understanding of healthcare ecosystem with respect to self-monitoring technology, the system engineering view is used. However, the focus in policies that facilitate developing the technological solutions in order to solve societal problem by using a roadmapping analysis.

3. Identifying the problem:

In 2014, 9.3% of the U.S population has diabetes. It accounts around 30 million people in America are diabetic [2]. More importantly, if this trend does not stop or slow down, the estimation, by 2050, one between ten people in U.S would have diabetes [3]. Those people are struggling with this disease in many way. The available technology is still not sufficient to measure their blood sugar in a sample and faster way. There are many obstacles to use these technologies such as the cost,

insurance coverage, and the technology distribution. Moreover, the delay routine for a diabetic patient is exhausted because he needs to think about measuring his blood regularly which leads to several issues such as psychologic aspect, thus, these challenges cause an overall social issues. Therefore, how policy can optimize the ecosystem for the current and potential diabetic people in U.S and accelerate the technology development in order to resolve these issues. Figure 1 shows, in general, the social issues with the current self-monitoring technologies that impact negatively on providing a healthy ecosystem for diabetic people [6], [7], [8], [13]. Also, policies related aspect contribute to the self-monitoring technologies such as the state's laws, insurance companies, and health providers system [1], [11]

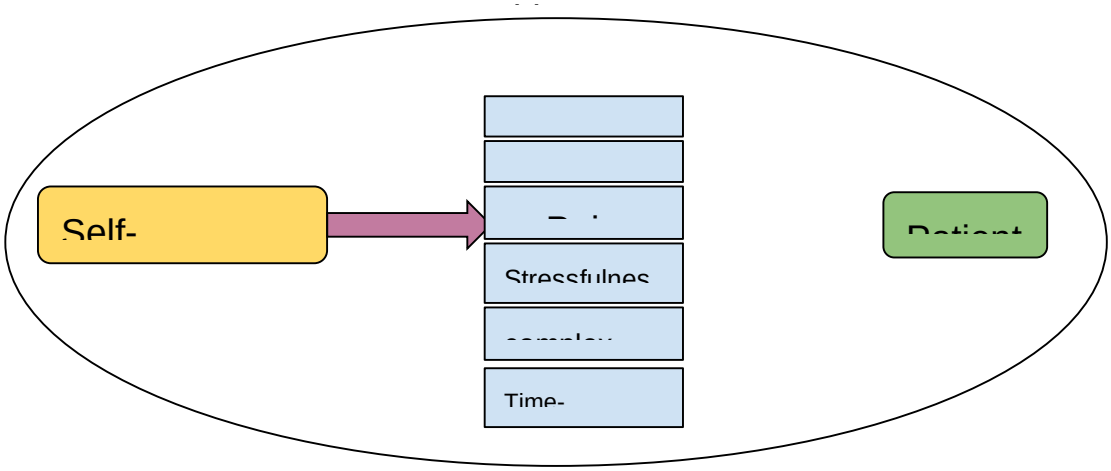

Figure 1

4. Methodology:

Technology Roadmapping analysis is used to build a strategic plan for glucose self-monitoring technologies. Roadmapping analysis addresses four elements, including societal drivers, targets, technology solutions, and resources. The societal drivers are the causes for developing the current technology. It examines the issues with respect to societal aspects. The target drivers are the customers or the users for a particular technology. The technological solution drivers are the solution for the societal issue by using technology, and it could be well-developed technologies or emerging technology. The resources drivers are the legislation or funding entities that are involved in dealing with the societal issue. A PCAST “System Engineering in Healthcare” and literature

review are used to evaluate and understand the technology, social and resources needs, and how can system engineering approach can be used.

5. National Institute Health Care (NIH):

This paper is using NIH as a federal agency that leads solving the diabetes disease issue by creating the policy, funding, gathering all stakeholders and so forth. NIH is a part of U.S department of Health and Human Services and it is the biggest biomedical research agency globally. It has fundamental goals such as innovation research strategies, expand knowledge, social responsibilities, the return of public investment in research, and so forth. [10]

6. Roadmapping Analysis:

In order to evaluate and improve the current policy to solve this issue, it is important to implement the roadmapping among 15 years from now with respect four primary challenging aspects that impact directly and indirectly the current and potential diabetic people in U.S as shown in table (1) below: societal driven, target, technology solution, and resources.

Roadmapping Analysis

Category	Now 2017-2022	5 Years 2022-2027	10 Years 2027-2032
Socitail Dr.	1- Pain 2- Cost 3- time- consuming 4- psychological aspect 5- Easy to use 6- Monitoring awareness 7- Contamination 8- Health providers 9- States laws	1- Insurance coverage 2- Decrease the psychological aspect 3- Monitoring awareness 4- No pain 5- low cost 6- Fast measurement 7- Easy to use 8- Less contamination	Healthy ecosystem
Target	Diabetic people	Potential diabetic people	Potential & Diabetic people
Technology Solutions	1- Self-monitoring devices using blood sample 2- 80% Accuracy	1- More advanced Technology 2- Apps (Programs) 3- Training 4- 90% Accuracy	More advanced Technology with 100% accuracy
Resources	1- NIH funding 2- FDA	1- NIH funding 2- Expanding the market	1- NIH funding 2- Expanding the market

Table (1)

The primary objective for the roadmapping in table 1 is to have a healthy ecosystem for people in U.S who suffer from diabetes disease by targeting the current and potential diabetic people with facilitating and expanding the market for more advance technology among funding from a federal agency. In social drivers, it is significant to study what kinds of social issues that impact positively and negatively those people. It is important for a federal agency to consider nine aspects, which are

pain, cost, time-consuming, psychological aspect, easy to use, monitoring awareness, contamination, health providers, and state laws from from 2017 to 2022. From 2022 to 2027, the federal agency should be able to consider eight aspects which are insurance coverage, psychological decreases, monitoring awareness, painless aspect, low cost, quick measurement time, easy to use, and less contamination. From 2027 to 2032, the federal agency should achieve a healthy ecosystem for the potential and current debates people in U.S.

To evaluate the category in table 1, it is important to be evaluated individually as shown in Table (2).

Social Dr.

Category	Drivers	Definitions	Codes	Weight
Patients needs	Pain	Avoiding finger prick	S1	10
	Cost	Can't afford the current cost, and buy stips regulary	S2	10
	Time-consuming	Reducing the result time waiting	S3	6
	Psychological aspect	Stressful and high pressure of thinking about their sickness	S4	8
	Easy to use	Devices need clean strips & specific amount of blood drop Redoing the test in case of accidents. Forgetting to measure the blood sugar	S5	7
	Monitoring awareness	Not aware of the important for blood measuring	S6	5
	Contamination	decrease the probability to get infection	S7	5
Policy	State laws	The lack of unifying and assuring that all states laws are inducing their providers and patients to switch from the old blood sugar to the new technology measurement	S10	9
	Insurance companies	The lack of covering the current and new technology in measuring the blood sugar, and the low benefits from this covering	S11	10
	Health service providers	The discouraging from all providers to advise their patients to use the current and new technology	S12	8

Table (2)

The social drivers, in table (2), are divided into two main categories which are patients needs and policy in order to examine what kinds of policy that should be developed. There are seven sub-drivers under the patient's' needs, which are pain, cost, time-consuming, psychological aspect, easy to use, monitoring awareness, and contamination, with their definitions and weights. The policy which impacts negatively the social issue is divided into three sub-drivers which are state laws, insurance companies, and health providers, with their definitions and weights. The definitions and weights for each sub-drivers are observed from literature review. As a result from the

measurement for these sub-drivers, the most important patients needs are reducing the cost and taking-off the pain in measuring the glucose blood [13]. On the other hand, the primary sub-driver for the policy is the differences of insurance companies coverage with respect to self-monitoring technology [11].

Target

Category	Drivers	Definitions	Codes	Weight
Goal 1	Diabetic people	People who have diabetes	T1	10
Goal 2	Potential diabetic people	People who have family history of diabetes or diagnosed as prediabatic	T2	10
Goal 3	Potential & Diabetic people	All potential and current Diabetic people in U.S	T3	10

Table (3)

To evaluate the targeted policy which will be developed to solve the social issues. Table (3), is divided into three sub-drivers with three main goals which are under the main objective for this paper providing a healthy ecosystem. First, solving the diabetic people issue, then, being prepared to solve the potential diabetic people issue, lastly, having the ability to solve both of them. All of these sub-drivers are defined in table (3), and the weight for each of them is 10 which is high.

Technology Dr.

Category	Drivers	Definitions	Codes	Weight
Current & New technology	Contact devices with patients	Self-monitoring technologies which are the available technologies that can measure the blood glucose level with painless and contact with patient's body such as sensory technologies or not using finger pricking.	G1	10
	Not contact devices with patients	More advanced Technologies which are the new technologies that are more convenient and not contact with the patient's body such as screening	G2	10
Connectivity	Apps (Programs)	The ability to transfer information.	G3	9
Education	Training	Training patients to use the technology correctly.	G4	7
Technological characteristics	Accuracy	The high quality of the measurement result.	G5	10

Table (4)

Because the policy should be developed to solve the social issue, it is significant to evaluate the

technologies' features that can resolve the social issues in U.S. Table (4) is divided into four categories which are the current and new technology, connectivity, education, and technological characteristics with five sub-drivers under these categories which are contact devices with patients, not contact devices with patients, Apps (Programs), training, and accuracy [12]. It can be seen that the contact devices with patient's body such as the current self-monitoring devices, the not contact devices with the patient's body which are more advanced technology such as screening, and accuracy are the most technology drivers, ranking highly in 10, that support the ecosystem for diabetic people in U.S. Because, from now to fifteen years, it will be more advance technology that appears in the market with more accuracy than the current self-monitoring devices which are not 100% accurate, these devices should be more reliable to use by the patents. Also, the devices accuracy will increase incrementally until reaching a 100% accuracy in fifteen years.

Resources Dr.

Category	Drivers	Definitions	Codes	Weight
Funding	NIH funding	The National Institute of Health, a federal agency that funds diabetes technologies, gathers stakeholders, expands the market, and leads creating the policy.	R1	10
FDA	FDA regulation	Reducing the regulation time for new technology	R2	10

Table (5)

Resources are federal agencies that can create policies and have authority to set up regulations relating to self-monitoring technologies. Also, they are able to fund and support technology development. Table (5) is divided into two categories funding and FDA (regulation). It shows that funding is significant to support research, current and new technology, expanding the diabetes devices market, and so forth that solve the diabetic people issues and to achieve the target for this paper. Funding is divided into one primary sub-driver, which is selecting a federal agency for funding which is NIH, and expanding the market for the current and new technology with high weight. Additionally, FDA can impact the technology development by adding or reducing

regulations. Since the FDA is a federal agency, it has authority to limit the painful technologies and support painless technology.

7. Discussion:

7.1. Priorities:

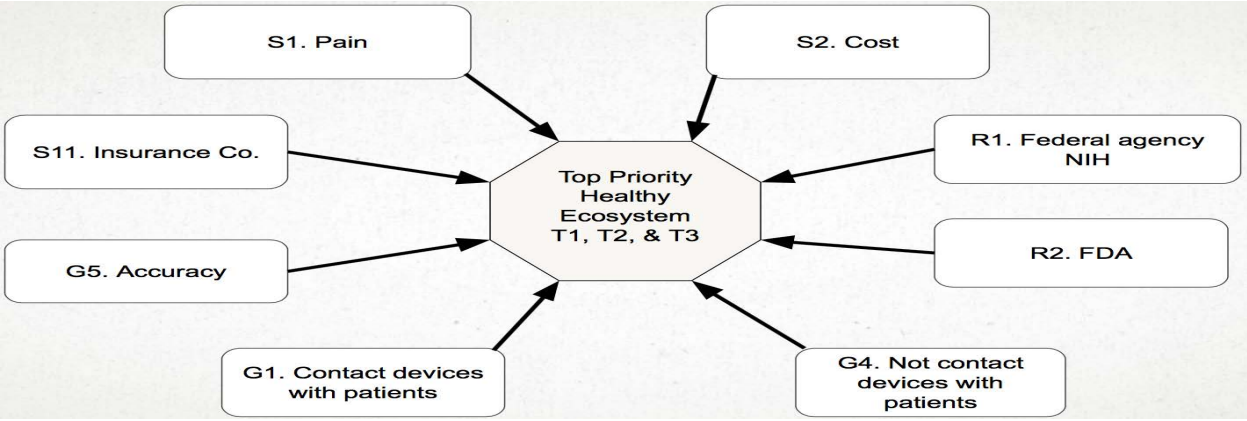

Figure (6)

After evaluating the primary drivers, in figure (6), with their sub-drivers, it is clearly that there are eight aspects that should be solved in now period of time. The drivers that ranks high, 10, in the analysis are: Pain, cost, insurance companies coverage, patient contact necessity, accuracy, and the federal agency NIH which creates the policy. However, all these drivers can not be achieve in a single period of time, thus, the upcoming suggestions are a roadmapping timeline leading NIH to achieve solving the ecosystem issue from now to 15 years.

7.2. Roadmapping Timeline:

Drivers/Time	Now (2017-2022)	5 Years (2022-2027)	10 Years (2027-2032)
Social	S1. Pain	S2. Cost S11. Insurance Co.	Healthy Ecosystem
Target	T1. Diabetic people	T2. Potential people	T3. Potential & Diabetic people in U.S
Technology	G1. Contact devices with patients & G5. 80% Accuracy	G2. Not contact devices with patients & G5. 90% Accuracy	G2. Not contact devices with patients & G5. 100% Accuracy
Resources	R1. NIH Funding R2. FDA	R1. NIH Funding (Creating policy, gathering stakeholders, expanding the market, ...etc)	

Table (7)

Table (7), shows the suggestion timeline to implement the policy from NIH to afford a healthy ecosystem for the current and potential diabetic people in U.S. NIH has the capability to induce and

expand the diabetes technology market by gathering all the stakeholders including private sectors, government, scientists in universities, and non-profit organization in order to gather all the financial and nonfinancial requirements which spreads the current and new technology in the U.S market. Thus, all of the previous main drivers, which are social, target, and technology, can not be solved and appeared without understanding the resource drivers that support all of the drivers. First target, from now to 5 years later (2017-2022), NIH should make sure that the FDA regulation fits with technology development for current and new diabetic devices. FDA is critical component in this system. The regulation regarding pain mechanism in technologies should be addressed, and technologies should improve the quality of patient's life standards. Therefore, encouraging the painless technologies is important to develop a new painless technologies. In the same time, NIH should start to fund, such as in technology researches, expand the market, and gather the stakeholders in order to create the policy. It will lead to afford the current self-monitoring devices which is contacting with patient's body in the market for the diabetic people with painless with 80% accuracy [9]. Even though these devices will be painless in the first five years, the price will stil high to purchase. However, from five to ten years (2022-2027), NIH will have the ability and time to reduce the cost and understand related companies obstacles. Because the market will be already expanded leading to have more devices in the market with various costs, features and 90% accuracy, the competitions between the technology companies will be so high in the devices price and quality. This will create another competition between the insurance companies by including diabetic devices in their plans to acquire more clients and raise their market share from this opportunity. As a result for this period of time, the technology companies will launch more advanced device because of NIH funding, the cost will be less than before for people who do not have an insurance plan, the insurance coverage plan will include the new devices, and it will eliminate the suffering for the potential diabetic people. Also, this period of time NIH will test the result for their policy and its impact to the social and the diabetic market. Therefore, from ten to

fifteen years later (2027-2037), the high device's accuracy,100%, should be achieved. Moreover, if the test is positive, the whole ecosystem for the current and potential diabetic people in U.S will be healthy. If not they should revise their policy. however, if the result is positive or negative, NIH funding and expanding the market should not stop because there are always more advance technology in the future that should be supported to not have a non-healthy ecosystem for diabetic people, thus, it should start from the beginning of the timeline to after fifteen years. Also, after solving the insurance coverage issue between five to ten years (2022-2027), it is important to follow-up that the insurance plans are still covering the people to not have the same issue again as well as the more advance technology with high accuracy to not stop the acceptance for using these technology by diabetic people.

Furthermore, insurance sector is various towards paying the cost of this devices. a same insurance company can vary its plans according to state's laws because the insurance plans cover only the direct diabetes treatment excluding the supplies or additional devices. However, in 2016, the District of Columbia and 46 states released a law that requires health insurance to cover diabetes treatment, and implementing this law differs. Some states do not make it mandate, while others impose the law to the basic treatment. The majority of states require the health insurance policy coverage to have direct and indirect diabetes treatment including self-monitoring devices [11]. A good example for how policy can induce and develop the ecosystem in any health issues from societal perspective is the electronic breastfeeding pump which spreads the breastfeeding among women by creating a policy that induce the insurance companies and hospitals to cover this device.

8. Conclusion and Recommendations:

8.1. Conclusion

Health care system is complex and interconnected. Developing new technologies can not work without considering the healthcare sector as a whole system. Therefore, one policy or one technology is not adequate to solve self-monitoring technologies issues. Policy makers need to understand the ecosystem of health care sector and act accordingly. The solution is a full package of

policies that touch several components in health care system such as insurance, conventaint, and safety aspect.

8.2. Recommendations:

- Federal government should require the states to generalized Insurance plans across the country.
- Patients should have ability to choose monitoring devices.
- More funding to reduce the cost of advanced technology to accelerate the market adoption.
- Support technology transfer to solve the current issue with the current technologies.
- Technology regulations need to be reconsidered to eliminate painfulness aspect in self-monitoring technologies.

9. Limitation and future work:

This paper has many limitations which are: the ranking process should be done by subject matter experts. However, for the seek of the time, the authors did the ranking based on the literature review. Another limitation is that a deep investigation for roadmapping would be a good future work to gain more understanding and cover all the aspect more effectively.

10. References:

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Appendix

Roadmapping Analysis

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FDA	FDA regulation	Reducing the regulation time for new technology	R2	**10**

Table (5)