

## Evaluation of telemedicine in management of elderly patient with CHF, living in senior living house

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Despite medical therapy advances and new diagnostics tools, there is still a need for more efficient treatment, especially new technology-facilitated models of care delivery. Efficient delivery of treatment and therapy can prevent complications, chronic disease and mortality. It would produce short and long term economic benefits to the patient, healthcare system and society. Heart failure represents, one of major cause of mortality and morbidity in industrialized countries. The incidence of heart failure is estimated from 1 to 5 cases per 1000 population with exponential increase in the population over 65 age, because of what heart failure is considered a disease of aging. The cost of management of heart failure represents a high burden to the healthcare system and is considered a major problem of public healthcare system. High incidence of re hospitalization due to frequent chronic heart failure ( CHF) exacerbation, makes this group of patient prone to depression and social isolation that deprive their quality of life.

With the aging process we can expect an increase of incidence of heart failure, with an associated increase of healthcare spending. In near future the elderly will represent one third(1/3) of total population, it is estimated that aging process by 2050 year will achieve 33% of elderly population over 65. Hence, well being of the society will be associated, with of quality of life that will be offered to this group of population. Despite the efforts of national healthcare system to show a decrease in incidence of CHF, the further augmentation of population over 65, will make this task even more difficult to be achieved. Therefore is obvious that management of CHF patient needs an alternative model in order to provide qualitative and efficient healthcare services to the elderly. The management of elderly who are deprived of any kind of home care, requires social inclusion of this marginalized person, through a collaborative partnership between healthcare institution, senior living house and society. A senior living houses are provided by Public Healthcare Social System. The recent increase in demand for senior house living house, flowered development of private sector senior living house. Disease management presents optimization of clinical management functions that include monitoring, follow up and specialist consultation (Heinzelmann, 2005). In the management of chronic disease, these functions are considered as bearing the highest direct and indirect cost of healthcare system. To show that telemedicine has a positive impact on healthcare outcome, it is necessary to demonstrate the appropriateness of the treatment and its outcome as being equally good, if not better, when compared to conventional treatment and its health outcome.

**Tab 1- Aging Population Prognosis**

Year	Average number of children per fertile women	Life expectancy at birth		Division of population per year group (percentage)			Group index of elderly (percentage)	
		m	f	0-14	15-64	65+	Non auto sufficient	In a need for senior living house, hospice
2002	1,27	77,1	83,0	14,2	66,8	19	49,6	28,5
2005	1,32	77,6	83,2	14,1	66,1	19,8	51,1	29,9
2030	1,48	81,0	83,6	12,2	60,3	27,0	64,0	44,0
2050	1,60	86,6	88,8	12,7	53,7	33,6	86,0	63,0

**Chronic heart failure -an important impact on public healthcare**

The heart failure represents a terminal syndrome of heart function deterioration, often affected by number of pathology associated with process of aging. Nevertheless, it has an important effect on long life perspective and quality of life characteristics. About 2 % of population in industrialized country are affected by heart failure, with average age at diagnosis of 76 years. The prevalence increase with age : 2% in person from 40 to 59 years, more than 5% in patient between 60 and 69 years and 10% in person more than 70 years old (Rozzini, 2004). A heart failure is considered a cause of 20% of all re hospitalization generated by patient's over 65 years. The cumulative mortality for CHF is estimated as 20 % death rate in first year after diagnosis and 50% death rate within 5 years after diagnosis.

The cost of management for CHF patient presents an important percentage of total healthcare spending. The Italian yearly spending for heart failure is estimated at 393.212.000 euros.(Politi, 2005)

A hospitalization rate of Italy for elderly group among 65- 79 years is estimated about 12% with the highest cost for re hospitalization for the patients between 75-79 age. The cost of heart failure care is estimated as percent of total healthcare spending equal to 1,3% ,with the highest cost spent for hospital care that represents 77% of total healthcare spending for heart failure (Politi, 2005). The major causes of re-hospitalization are, non adherence to treatment and non adherence to physician advices.(Temistocle Study, 2003).The heart failure NYHA classification measures the extent of heart dysfunction, a rate of mortality vary by NYHA groups, estimated at 15%-40% for NYHA II-III in 1-4 years. The heart failure represents a principle cause of mortality and invalidity and is main cause of

hospitalization for patient over 65 years.

Despite of tendency to decrease, the heart failure incidence do not show a real evidence that CHF incidence is diminished in last 30 years, indicating that heart failure epidemy didn't diminished and that data reported are underestimating complexity of the epidemy ( Rozzini , 2004)

**Senior Living House – Italy**

A senior living house are residential structure that accept an elderly who is partially or complete non auto-sufficient. The objective of senior living house(SLH) is to guarantee physical health and psychological well being, to promote personal autonomy,to stimulate interest and social relation. Despite the definition of (SLH) that indicates that this type of facilities,should provide a medical geriatric, nurse and rehabilitation assistance. In Italy the senior living houses lack an adequate healthcare professional support, therefore we want to address a concern about SLH capability to provide an adequate well-being without an additional healthcare-social system support.The percentage of elderly population who resides in senior living house vary by country.

**Tab 2- Percentage of elderly assisted by senior living house in selected European countries**

Country	Percentage of elderly assisted by senior living house	
	year	%
Belgium	2004	8,1
Netherlands	2008	6,8
Norway	2006	5,6
Italy	2005	3,0

Source : OECD

Contemporary senior living house in Italy are experiencing process of reorganization. The reorganization process will transform (SLH) for elderly who are auto-sufficient to (SLH) dedicated to non auto sufficient elderly group, with an additional decrease of number of beds from 6,4 beds (per 1000 elderly) to 3,3 beds (per 1000 elderly) and an increase of healthcare system cost coverage from 50% to 60%. The italian healthcare – social system provide three type of healthcare assistance for the elderly.

**Tab 3- Types of healthcare – social assistance for elderly in Italy**

Health therapeutic residence	Accepting the patient in convalescent phase of disease or after hospital's discharge who are not auto sufficient or is affected by chronic pathology that hasn't been stabilized yet.
Senior Living house ( RSA-italian)	Accept the patient with stabilized pathology but who suffers from polichronic disease and needs intensive health care and nurse assistance support.
Residential	Represents low level of assistance for the patient with stabilized pathology but not

assistance	auto sufficient
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Source: Franco Pasaresi (2011)

**Tab 4-Cost of Senior living house per patient in 2011 ( euros)**

	National healthcare service	User – Elderly	Society	Total
Yearly cost	1.428.140.118	1.305.516.956	68.456.040	2.802.113.114
Monthly average	1505	1375	71	2951
Percentage	51.00%	46,6%	2,4%	100.00%

Source: Franco Pasaresi (2011)

In Italy exist 95 734 senior living house provided by National and Regional Healthcare- Social system. The Italy is experiencing an increase of privately managed senior living house, stimulated by an increase in demand from the patient who is non auto-sufficient, affected by complex pathologies. With an obvious increase in demand and waiting list, it is necessary to address the future provision of adequate social and healthcare assistance to this specific usually marginalized group of elderly. The cost of senior living assistance has a trend to increase with further associated population aging, this fact imply necessity to develop a new model of healthcare delivery that will provide competent assistance with adequate cost containment to elderly living in SLH.

**Disease Management – Role of telemedicine**

The disease management presents, a promise in reorganizing chronic care and optimizing patient outcomes. American Heart Association’s Disease Management Taxonomy Writing Group developed a system of classification for disease management programs among 8 domains defined by American Heart Association, we will mention only next four : method of communication, intensity and complexity, environment and clinical outcomes, where we believe that telemedicine can offer benefits over usual care. The high cost of inpatient stay, is great burden to every national healthcare system. The possibility of shifting patient care from hospital facilities to home-care or senior living house would reduce healthcare spending. In situations, where the patient might need immediate support in emergency situations, automated home monitoring, physiologic monitoring of signs and symptoms, or two-way video monitoring with or without physiologic monitoring, with the recognition of an information society as the future model in governmental and community participation, telemedicine is becoming an important service that would enable the inclusion of all the resources necessary in providing healthcare services at home or any other location.

Different disease management model have tried to achieve better maintenance and monitoring of patient with CHF with no success.(Jerant, 2001). The medical and social factor correlate with readmission or death events in patient with CHF ( Chin, 1997).The hospital's readmission for patient

with CHF correlates with multiple comorbidities exacerbation and an inadequate patients adherence to the treatment (Chin,1997) and can be safely monitored and corrected via telemedicine.

The disease management for chronic heart failure needs an integrated model of care,that integrate hospital and territory assistance. The evaluation of home care management model that has involved general practitioner as gate keeper in evaluation of patient's need for secondary care (cardiologist assistance), shown a good collaboration among GP and cardiologist and high level of diagnostic accuracy (Campana, 2008).

Hence, it is important to create new assistance model of integrated disease management, with objective to diminish re hospitalization,healthcare spending and improve QoL of elderly. Telemedicine can provide a model of real-time integration between general practitioner, cardiologist, internist specialist. Telemedicine has showed to be effective in improving the patient health status and decreasing re hospitalization.( Scalvini , 2009).

### **Social Inclusion – role of telemedicine and previous experience with telemedicine in CHF patient**

The behavioral factors such as poor compliance to the medication and prescribed diet, a lack of education and social isolation are major causes of heart failure exacerbation, an interactive system of home physiologic and clinical monitoring combining telecommunication technology and medical device for transmission of vital signs measurement can decrease readmission rate and improve social well being ( Rich , 1995, Shah 1998)

Telemedicine can offer realtime titration and adequate dosing of medication through tight follow up of the patient symptoms. An underusage of ACE inhibitor has been shown to correlates with higher rate of hospital readmission ( Luzier, 1998). The close monitoring via telecommunication from a remote location can prevent re-hospitalization for the heart failure patient, who has been recently discharged, ambulatory outpatients and among both elderly and middle aged persons( Shah, 1998).In previous years, research has showed that tight home care monitoring, improves functional status of the elderly( Antonicelli, 2008), the trial conducted by Kornowski (1995) who evaluated a weekly home visit by internist specialist has shown a significant decrease of readmission to the hospital,improved functional status of the patient, with consequent decrease of healthcare expenditure. With development of ICT, opportunity to provide healthcare on the distance, to the patient with CHF would have additional advantage over research done until now.

The regional Healthcare unit of Marche ( Italy ), conducted a study that has evaluated the cost of CHF in region Marche,Italy ; 17.870 patients with CHF have been identified out of 1,5 million inhabitants in Marche Region (1,2% prevalence rate). The total health care costs were estimated around €27,5 million in 2003. A hospital care, drugs and outpatient care have been represented as percentage respectively 77%, 21%, and 2% of the total costs.

## **Clinical trial**

We have proposed to regional authority a clinical trial in order to estimate impact of telemedicine in elderly population affected by CHF who are living in senior living house.

*Primary Objectives:*To evaluate superiority of telemedicine versus standard care in optimizing therapy, improving patient compliance to the therapy, and reduction of clinical cardiovascular outcomes /hospitalization in senior living house setting

*Secondary Objectives :*To evaluate Quality of life using MlWHF and MAST model

### *Definition of patient*

The patients over 65 age who live in senior living house are considered as our target group, as they have the highest incidence of hospitalization of 20%,they represent the important cost burden to healthcare spending.A senior living houses have an inadequate medical professional care,therefore are incapable to provide necessary assistance to the non auto- sufficient patient with CHF as well as to the patient with complex comorbidity.A patient with New york Heart Association(NYHA) II and III stand for a patient with hemodynamic instability and lower quality of life, but not terminally ill. We consider that senior living house environment represent an adequate setting to test telemedicine approach, as the patient living in senior living house necessitate frequent and continuous monitoring and pharmaceutical- drug titration adjustment. We consider that the patient who is living in senior living house miss an adequate healthcare assistance, and would have the greatest benefit from continuous monitoring and telemedicine. The previous telemedicine randomized clinical trail have been shown a decrease of negative cardiovascular events and quality of life improvement for the patient NYHA II- III.

### *Inclusion Criteria :*

1. Patient with Heart failure diagnosis based on guidelines ESC
2. Patient over 65
3. Patient NYHA II - III
4. Patient with Ischemic heart
5. Patients with valvular heart pathology
6. Patient with hypertensive and dilatative cardiomyoptahy
7. EF= 35%

### *Exclusion Criteria :*

1. Patient below 65 years
2. Patient with recent MI

3. Patient with psychiatric disease and dementia
4. Patient with Chronic renal failure
5. Anorexia, patient on dialysis
6. Non cooperative patient

### *Study Design*

A randomized 2 parallel group with ratio 1:1, duration of study would be 12 months. The both groups interventional – Telemedicine and Usual care will have next 3 visits:

1<sup>st</sup> visit- baseline visit

2<sup>nd</sup> visit at 6 months

3 visit 12 months

Additionally Interventional group – Telemedicine group will have next measurements :

1. Weight and blood pressure every day and will be send via software platform to the cardiologist.
2. ECG will be measured weekly and send to the cardiologist for evaluation.

### *Sample size calculation*

To calculate sample size we used the results obtained in previous studies that have showed superiority of telemedicine versus usual care for overall hospital readmission rate. In order to show superiority of interventional group, the difference that we expect to be detected is 20% ,we assumed 50 % of re hospitalization due to all causes in usual care group and 30% in telemonitoring group over a 6 month period. The previous studies conducted using randomized clinical trial design showed decrease in readmission of 20- 40 % ( Clark, Cleland, Dendale). For the study 80% powered at the 5 % level of significance to detect difference and to show statistical superiority we need 120 patient including 20 % drop out.

### *Subgroups*

We consider important to evaluate impact of telemedicine in subgroups of total sample, who are affected with different comorbidities and are under different therapeutic regime, in order to establish where, when and to who telemedicine approach can be cost effective. Therefore next subgroup evaluation will be conducted:

1. Diabetes vs no Diabetes,
2. Hypertension vs no Hypertension
3. Ischemic CM vs no Ischemic CM,
4. Ischemic cause vs no ischemic cause,
5. B blockers vs no blockers,
6. ACE inh vs no ACE inh

7.Systolic dysfunction vs no systolic dysfunction

8.dose of loop diuretic (40 mg vs. >40 mg/day)

### *Telemedicine Equipment*

The multidisciplinary platform for telemedicine, that supports multispecialist teleconsultations and home care will be used. The software allows realtime and storage and forward data sending using wireless connectivity, it integrates a different type of medical devices tailored for the patient use. It also permits a patient or nurse easy and convenient utilization from its own home place. A physician communication and consultation are supported with archiving, reporting, real time communication and high resolution of the documents.

### *Quality of life Evaluation*

The Minnesota living with Heart failure questionnaire will be used for evaluation of quality of life improvement. The Minnesota living with Heart Failure questionnaire is a patient self assessment measurement, being developed to evaluate the therapeutic response to intervention for heart failure.(Rector ,1987)

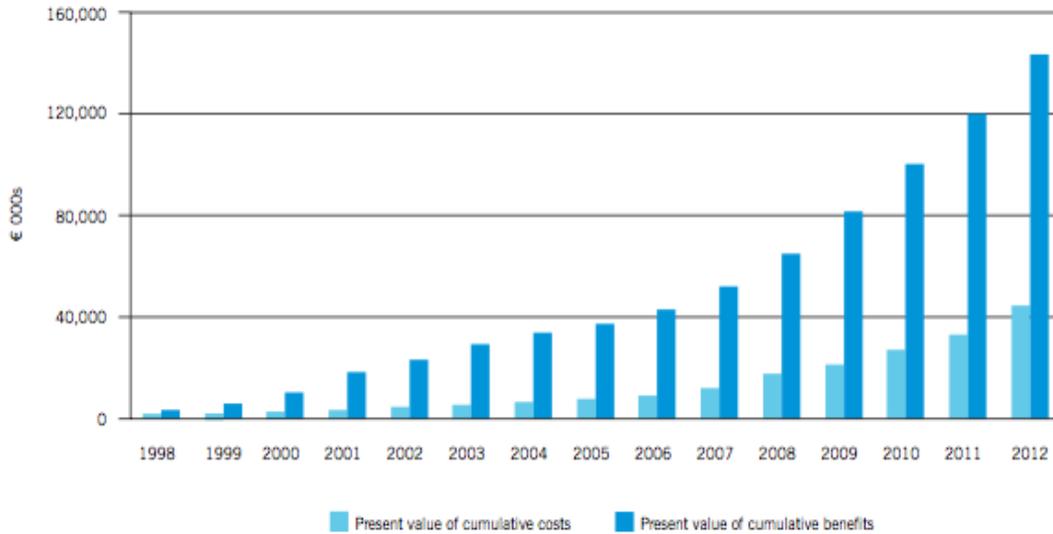
It is reliable, repeatable and validated questionnaire. A patient's perception of the effects of heart failure, combining physical and emotional questions to what patient rates his own perception of impairment would be measured using Minnesota living with heart failure questionnaire. The Minnesota living with Heart Failure questionnaire is considered valid indicator of therapeutic benefit of medication for heart failure during randomized clinical trial (Rector 1993)

### ***MAST model, ROI for telemedicine***

At the word "Healthcare", one immediately thinks about the growing economic burden. The leading cause of the huge healthcare spending comes directly from chronic disease. The direct and indirect cost of healthcare is increasing while a growing demand for these services seek a model for service delivery that would provide higher quality and better accessibility. An unequal balance between demand and supply for healthcare would produce an economic phenomenon of public failure due to the provider's inability to efficiently meet the market's demand for healthcare. With the evolution of society and technology, a tendency for increased life expectancy within that futuristic society, demands an effective, low cost and accessible healthcare service as the only appropriate model to correct the public failure of the system. The return of Investment on ICT technology has showed positive results, in some areas of industry. A level of Healthcare system investment in ICT is impeded with institutional and personal barriers. We consider necessary to evaluate return of investment on the end of study, in order to show an economical impact of telemedicine. A positive results regarding ROI for telemedicine are

already published and have been emerged from an evaluation of benefits and cumulative costs generated by telemedicine projects in cardiology over a period of 10 years ( Scalvini , 2003) and have been presented in graph.

**Graph 1- Telemedicine ROI ( Scalvini ,2003)**



The analysis of cost effectiveness for telemedicine are scarce, Setto(2008) conducted a review of randomized clinical trial for telemedicine in CHF patients, that have involved cost effectiveness analysis as part of study analysis .The table shows some study's results reviewed by Seto,we selected those that represent significant cost savings of telemedicine,and we would like to revalidate them in our study.

**Tab. 5 -Cost effectiveness analysis for telemedicine in CHF patient**

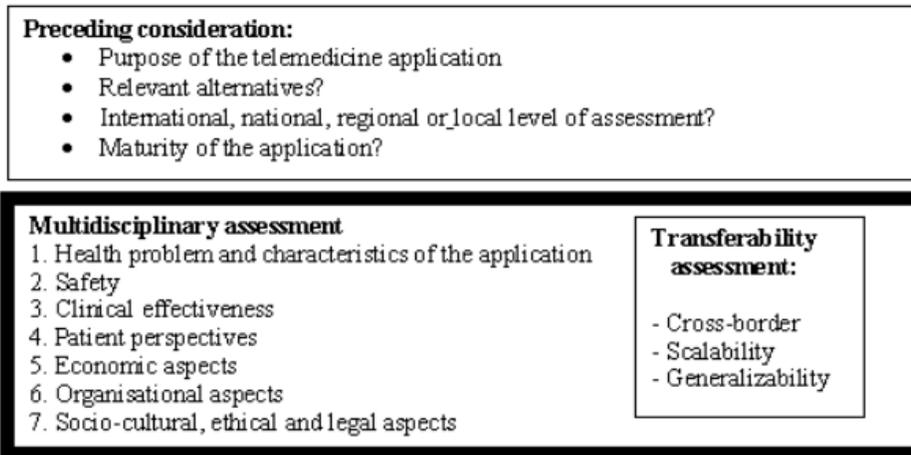
author	Events measured	The cost reported	Savings estimated for telemedicine group
Benater	Re hospitalization	Usual Care– 500,343 \$ Telemonitoring – 223,638 \$	55,3 % ( 6 months)
Jerant	Re-hospitalization and ER visits	Usual Care–93,686 \$ Telemonitoring – 29,701 \$	68,3 %
Scalvini	Re-hospitalization	Usual Care–140,874 euro Telemonitoring – 107,494 euro	23,7%

Source :Seto 2008

EU commission at beginning of 2012 has presented MAST model,a model has been born from the lack

of high quality evidence on the effectiveness of telemedicine, the scarce evidence has been considered a cause and main barrier for wider use of telemedicine. MAST model presents a multidisciplinary process that summarizes and evaluates information about the medical, social, economic and ethical issues related to the use of telemedicine in a systemic, unbiased, robust manner (Kidholm, ppt presentation of MAST model). MAST model evaluate 7 domains presented in box.

For more information about model <http://www.mast-model.info/>



## Conclusion

An intensive interventions that can provide early access to physician, real time diagnosis and therapy, improved frequency of contact and sustained follow up, can improve patient's clinical outcomes, quality of life and well being. The empowerment of a patient, by giving him an active role in patient - physician relationship and combining treatment interventions with education training can improve patient's self care. The promise of technology development allows a healthcare system to provide service in a simplified manner from a distance. If the government has a goal to achieve an economic scale and see the healthcare system efficient and liable, the cost of healthcare services provided need to decrease and productivity per unit of cost need to be reinforced. The added value of telemedicine's health-service delivery is characterized by lower cost per unit of service provided, better quality, better effectiveness and higher accessibility compared with conventional care. The process of aging will increase healthcare cost of service provided, if an adequate model of disease management that will optimize care and healthcare spending wouldn't be designed, it will be a difficult to provide an adequate healthcare service to every citizen in near future, especially to those in the greatest need. Therefore, telemedicine with an adequate return of investment and cost effectiveness that have to be established in future studies, can be an optimal model to achieve elderly population well being in senior living house.

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