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Selection of patients for further deployment
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Author:	Myriam Le Goff-Pronost
Reviewed by:	John Oates
Approved by:	Donna Henderson
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Abstract

This document outlines recommendations for the selection of patients who are most likely to benefit from home telemonitoring of blood pressure and for the evaluation of such a service.

Key Word List

Blood pressure, Logit analysis, recommendations

Executive Summary

This report presents some recommendations for the selection of patients who could benefit from home telemonitoring of blood pressure and for the evaluation of such a service. It is based on the results of the Vigisanté trial and an econometric analysis of the salaried employees who used the devices and Vigisanté platform. Seven recommendations are made:

- **Recommendation 1:** A programme of self-measurement of blood pressure will be more efficient if the patient is concerned by the pathology and hence will be more observant.

- **Recommendation 2:** It will be more efficient to previously identify the high-risk patients by a questionnaire (for example: HRA, Health Risk Assessment).

- **Recommendation 3:** For the evaluation process, there must be incentives for patients to be compliant with the good practices of home telemonitoring.

- **Recommendation 4:** The economic assessment will be more realistic if the technology is stabilised. Running the cost-effectiveness analysis during the development of devices and platform will necessarily disturb the economic results.

- **Recommendation 5:** An educational step for the devices and platform is necessary for the patients, and an introduction to the technology is essential for health professionals. This must be done before the evaluation period.

- **Recommendation 6:** The company can be an evaluation area for telemonitoring of blood pressure.

- **Recommendation 7:** We have to extend this type of assessment protocol and to reproduce the methods used in a larger sample.

Change History

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Version Changes
0.1   Initial draft
0.2   Minor updates
1.0   Minor amendments

Table of Contents

1. Introduction

1.1 Purpose of this document

The objective of this document is to identify profiles of hypertension patients who may benefit from the provision of telehealth services and for the evaluation of such a service. It based on the Vigisante trial.

We present the characteristics of patients who may benefit from telemonitoring of hypertension and some recommendations for further deployment from an econometric analysis. This report is based on the results presented in deliverable D9.2 Final Pilot Evaluation of the Vigisanté programme.

1.2 Background

Vigisanté is a project developed in response to a call for projects by the French Ministry of Industry, in connection with the Ministry of Health, on the management of chronic diseases by telemedicine. It concerns hypertension and associated risk factors. 4500 employees were screened and 649 patients included in this monitoring programme for hypertension. The programme objective was to measure the blood pressure evolution of salaried employees using a telemonitoring platform as compared to traditional measurement.

Vigisanté is a pilot project screening for hypertension in company employees, supported by a medicalised platform, combined with general practitioners (GPs) and telemonitoring of hypertensive patients at home. The pilot focuses primarily on the Nord-Pas-de-Calais region (North of France).

The objective of WP9 is to test in real-life conditions the set of telehealth services that have been selected for the management of patients suffering from hypertension. Hypertension has a significant impact on factors of cardiovascular risk. Remote monitoring tools through telehealth can reduce healthcare spending and absenteeism.

1.3 Glossary

BP	Blood Pressure
DBP	Diastolic Blood Pressure
GP	General Practitioner
HAS	French National Authority for Health
HBPM	Home Blood Pressure Monitoring
HBPT	Home Blood Pressure Telemonitoring
ICER	Incremental Cost-effectiveness Ratio
SBP	Systolic Blood Pressure

2. Background and methodology

2.1 Background

A patient is considered hypertensive if he has a blood pressure higher than or equal to a target threshold. Hypertension is defined by a systolic blood pressure ≥ 140 mmHg and / or diastolic blood pressure ≥ 90 mmHg. The management of hypertension is dependent on the severity of hypertension and associated risk factors.

According to the French National Authority for Health (HAS, 2005), the practice guidelines for blood pressure monitoring must:

- Confirm the diagnosis of hypertension.

- Conduct an initial assessment.

- Organise an information and consultation announcement of hypertension.

- Set-up lifestyle changes (and monitoring).

- Control of blood pressure in the first six months.

- Focus on five classes of antihypertensive drugs that have demonstrated prevention of cardiovascular complications.

- Individualise the choice of first antihypertensive treatment.

- Combine two active ingredients.

- Ensure good tolerance.

In the case of the Vigisanté programme, we are concerned with home telemonitoring of blood pressure. Parati and al. (2008) identified the advantages and the limitations of home blood pressure monitoring (HBPM) in the European Society of Hypertension Guidelines for blood pressure monitoring at home (Table 1).

Table 1: Advantages and limitations of home blood pressure monitoring[1]

Box 2. Summary of advantages and limitations of HBPM (modified with permission from [9])

Advantages	Limitations
● A number of measurements during the day and also over several days, weeks or months a are possible	● Need of patient training (short for automated devices)
● Assessment of treatment effects at different times of the day and over extended periods	● Possible use of inaccurate devices
● No alarm reaction to BP measurement	● Measurement errors
● Good reproducibility	● Limited reliability of BP values reported by patients
● Good prognostic value	● Induction of anxiety, resulting in excessive monitoring
● Relatively low cost	● Treatment changes made by patients on the basis of casual home measurements without doctor's guidance.
● Patient-friendliness (in semiautomatic devices)	● Normality thresholds and therapeutic targets still debated
● Involvement of patient in hypertension management	● Lack of night recordings
● Possibility of digital storage, printout, PC download or teletransmission of BP values (in some devices/systems)	
● Improvement of patients' compliance to treatment	
● Improvement of hypertension control rates	

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[1] Parati, 2008

Parati et al. (2008) said that "*HBPT shares more advantages of traditional HBPM while improving the quality of data and facilitating their interpretation*". This is the strategic rationale of Vigisanté. Vigisanté started off with the observation that blood pressure is as dependent on medication treatment as style life and home measure telemonitoring (HBPT).

De Luca (2005) showed that HBPT improves the control of BP and compliance with treatment. For Mengden (2004), HBPT is useful for faster identification of patients responding to treatment. Parati et al. (2008) confirmed that there is high cost of purchasing and maintaining the technology, but it can be "*partly counterbalanced by a reduction in the costs of patients' management compared with usual care*". Parati et al. (2008) recommended a minimum of 12 measurements and up to 25 during seven days, with at least two morning and two evening measurements.

2.2   Methodology

The results are based on the data derived from the Vigisante trials. The inclusion criteria for the intervention group were:

- Age > 18 years.
- Employees of companies benefiting from group health coverage with one of the three partner institutions.

The main clinical criterion was the systolic and diastolic blood pressure. The other clinical indicators were: heart rate, $SatO_2$ (%), weight, ECG (rhythm, QRS), comorbidity, medications and adherence rates. Depending on the enrolment date, the duration of follow up varied from 9 to 18 months (longitudinal data). Three main demographic data were collected: age, gender, and marital status. Clinical data were: measurement of blood pressure and heart rate, and if required, weight and medication compliance. Economic data were investment and exploitation data, as well as health expenses related to hypertension.

Employees included in the study are those for whom the existence of hypertension had been confirmed, either by self-measurement of blood pressure three times every morning and evening over a week, or by a series of measurements during a period of time defined by medical specifications.

Patient recruitment was conducted by Vigisanté support function in partnership with the departments of human resources supported by information campaigns and promotion. Among the 4,500 screening appointments made, 649 salaried employees were assessed for the project. We based our results on these 649 employees. For the economic assessment, the sample was lower, because we had to take into account the medical consumption which was available only in the Public Insurance Database.

The quantitative data were analysed through the statistical software SAS 9.2®. We used a logistic regression (Logit) in order to do the econometric analysis.

3. Project findings

3.1 Employee profile for the success of a hypertension telemonitoring programme

We considered in this analysis the salaried employees, so we have to take into account this specific group for the recommendations.

Among the 649 patients who used the Vigisante platform, 66% were men and 34% women. The average age of Vigisanté users was 48.8 years old (minimum 22, maximum 65). The average weight was 83,94 kg (minimum 42kg, maximum 146kg). 6.16% were diabetic patients, while 8.17% had a kidney disease. 40.5% of employees knew that they were hypertensive. Vigisanté allowed diagnosis of persons who did not know they were hypertensive (59.5%).

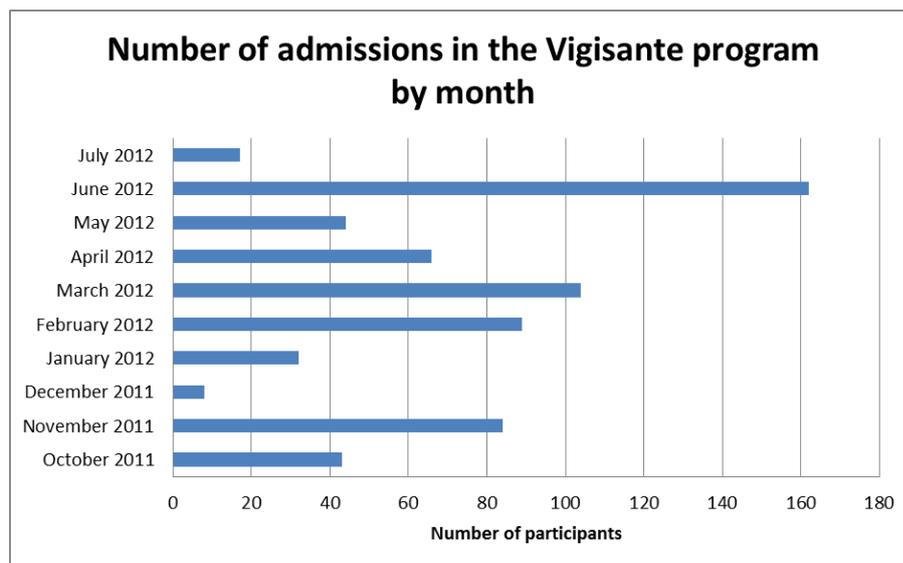The number of admissions in the Vigisanté programme is presented in the Figure 1.

Figure 1: Number of admissions in the Vigisanté programme by month

The average participation length was 231 days (about seven months); the minimum was one day, and the maximum 546 days (about 18 months).

If we consider the diastolic blood pressure (DBP), at admission 49% were considered as hypertensive patients. The same results were obtained from the systolic blood pressure (SBP). At the end of the participation of the patients, only 18% were considered as hypertensive patients. We confirm the result that hypertensive telemonitoring diminishes the blood pressure measurements.

We used a Logit analysis in order to identify the probability of having a lower DBP by using the Vigisanté platform and medical devices. This method can identify the profile of employees for whom Vigisanté was a medical success, that is, those for whom the Vigisanté programme succeeded in reducing blood pressure between the admission date and the final day of monitoring.

The hypothesis was as follows: the individual's characteristics have an influence on the success of the programme of hypertension monitoring.

The model assessed the probability of having a lower diastolic blood pressure at the end compared with the beginning of the programme; the same results were obtained for the systolic blood pressure.

The endogenous variable equals 1 if the diastolic blood pressure was lower at the end of the programme.

The explanatory variables were separated into three categories:

- Demographic variables: gender and age. Age was separated into three classes: less than 40 years old, between 40 and 55 years old, more than 55 years old.
- Clinical variables: weight, to be hypertensive at the beginning of the programme, and comorbidities (diabetes and kidney disease).
- Vigisanté variables: activity of the patient (only participation by the self-measurement of blood pressure or e-learning programme on dietary and hygiene devices), participation duration.

In order to model the factors of the programme success, we used a discrete choice model, a Logit model (Cramer, 1991).

In the Logit model, the endogenous variable – success of the programme – "success" equals 1 if the blood pressure is reduced and otherwise 0. "Success" is a binary variable. The Logit model is based on the Logit distribution whose cumulative probability distribution is given by the following expression:

$$P_i = F\left(a + \sum_{j=1}^{m} b_j X_{ij}\right) = \frac{1}{1 + exp\left[-\left(a + \sum_{j=1}^{m} b_j X_{ij}\right)\right]} \quad (1)$$

where P_i is the probability that an event will occur given a set of explanatory variables X_j, and b is a vector of coefficients. The empirical tests require rearranging equation (1) into the following form:

$$z_i = a + \sum_{j=1}^{m} b_j X_{ij} + e_i \quad (2)$$

where $z_i = ln\left(\frac{P_i}{l - P_i}\right)$

The econometric results are presented in the Table 2.

Table 2: Econometric results

	Probability of success
Constant	3.16 ***
Demographic variables	
Woman	- 0.1322
Age : less than 40 years old From 40 to 55 years old More than 55 years old	0.3506* -0.2260 *Ref*
Clinical variables	
Weight	-0.0137**
Not hypertensive at the beginning	-1.0922***
Comorbidities Diabetes Kidney disease	0.1168 0.1609
Vigisanté variables	
E-learning participation	-0.076

Participation duration
 	
    Less than 6 months
    Between 6 and 9 months
    More than 9 months
	
	-0.146
	0.406
	ref

Number	649

Notes:

    ***   Significant at 1%

    **   Significant at 5%

    *   Significant at 10%

The results show that the most important variable is the health status of the patient: if the patient is hypertensive at the beginning of the project, the probability of success (reduction of the blood pressure) is higher. So, we can assume that a hypertensive patient is more involved in the programme to obtain the target measure of blood pressure.

However, the greater the weight, the less is the probability that the programme reduces the blood pressure. These are patients for whom cardiovascular risks are significant, so the monitoring of the blood pressure must be complemented by direct contact with GP or specialist.

The younger patients, less than 40 years old, have a higher probability of success than those over 55 years old. Two effects can explain this: the earlier medical intervention, and the appropriation and acceptance of a medical device which can help them to be more observant.

In this study, gender, co-morbidities, participation duration, and type of activities are not significant.

> **Recommendation 1:** A programme of self-measurement of blood pressure will be more efficient if the patient is concerned by the pathology and hence will be more observant. So that,
>
> **Recommendation 2:** It will be more efficient to previously identify the high-risk patients by a questionnaire (for example: HRA, Health Risk Assessment).

The main advantage is the fact that self-measurement leads to better control of blood pressure. Taking several measures reduces the variability in effect, and provides a better estimate of the "true" blood pressure for diagnosis and monitoring. In addition, the blood pressure measurement performed by the patient at home removes the "white coat effect" and the "masked hypertension", thus allowing a better classification of cardiovascular risk. This is true if the patient is in compliance with the good practices (number of measurements, at the time specified, etc).

> **Recommendation 3:** For the evaluation process, there must be incentives for patients to be compliant with the good practices of home telemonitoring.

Finally, it allows the patient to be an actor of his own health, and to facilitate blood pressure measurements by avoiding patient travel to the GP's office. And the telemonitoring programme must be complementary to the coordinated healthcare circuit.

3.2 Recommendations from the previous analyses (D9.2)

3.2.1 Results from the economic assessment

The cost-effectiveness analysis in this study assessed the contribution of the implementation of the Vigisanté programme compared to traditional monitoring by a GP.

We have demonstrated that the Vigisanté programme is dominated by the traditional monitoring programme, which means that this screening and monitoring programme for hypertension at home is more expensive and less effective. We saw in the sensitivity analysis that 85% of simulated ICER were in the northwest quadrant, which means that the strategy implemented was dominated whatever the collective willingness to pay.

Care consumption was less in the Vigisanté group, notably in terms of medication and consultation. But the costs were significant. Vigisanté invested time and money in research and development concerning the devices, which is why the cost of the infrastructure was high, which therefore implies a bias in the results of the cost-effectiveness.

> **Recommendation 4:** The economic assessment will be more realistic if the technology is stabilised. Running the cost-effectiveness analysis during the development of devices and platform will necessarily disturb the economic results.

3.2.2   Results from the satisfaction analysis

The implementation of Vigisanté met the expectations of patients and health professionals.

From the patients' point of view, the medical information present in eHealth programmes can improve diagnosis and treatment. 59% of patients involved in the project experienced an improvement in their health, 80% were satisfied with the follow-up of their hypertension monitoring and support, and more than 80% of attendees would recommend it to friends or family.

From the physicians' point of view, the implementation of such a service strengthens the role of the GP. The study shows that for about 69% of GPs, the integration of patients into Vigisanté allowed global health benefits, including blood pressure. But only 19.6% of GPs used the Vigisanté portal. The Vigisanté portal was seen by GPs as too complicated; they did not have the time to learn how to use it because of their busy schedule.

> **Recommendation 5:** An educational step for the devices and platform is necessary for the patients, and an introduction to the technology is essential for health professionals. This must be done before the evaluation period.

4. Conclusions

Blood pressure self-assessment is nowadays a reference practice, and the telemonitoring of the blood pressure measurements must lead to a better observance of treatments with fewer complications and an integration of medical care coordination.

The company is an interesting health territory which can be suitable for the diagnosis of hypertension, because the blood pressure measurement is simple and non-invasive. The next step could be a connected watch and wristband worn by salaried employees to make an ongoing analysis of their health status.

Recommendation 6: The company can be an evaluation area for telemonitoring of blood pressure.

Concerning the assessment of the project, we have worked on a small sample (because of the loss of patients when we added some databases, for example the national database of care consumption). The duration of the study was only six months. For a chronic pathology, it is useful to have a longer period of monitoring. However, this analysis provided further information.

Recommendation 7: We have to extend this type of assessment protocol and to reproduce the methods used in a larger sample.

The U4H programme is great example of the mutualisation of data and evaluation protocols, notably by the randomised controlled trials of sufficient power considered in the other trials.

Appendix A: Bibliography

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