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## VIGILANS, A REGIONAL INTEGRATED ACTION-RESEARCH PROGRAMME TO PREVENT SUICIDE AND SUICIDE REATTEMPT IN SUICIDE ATTEMPTERS SETTING, IMPLEMENTATION AND EVALUATION

Journal:	BMJ Open
Manuscript ID	bmjopen-2018-022762
Article Type:	Protocol
Date Submitted by the Author:	19-Mar-2018
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Keywords:	prevention, Suicide & self-harm < PSYCHIATRY, crisis management, organization of healthcare, Telemedicine < BIOTECHNOLOGY & BIOINFORMATICS

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# VIGILANS, A REGIONAL INTEGRATED ACTION-RESEARCH PROGRAMME TO PREVENT SUICIDE AND SUICIDE REATTEMPT IN SUICIDE ATTEMPTERS SETTING, IMPLEMENTATION AND EVALUATION

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**Number of figures:** 3

**Number of tables:** 1

**Word count:** 4813

**Keywords:** prevention, suicide, crisis management, organization of healthcare, telemedicine, emergencies

**Abstract**

**Introduction.** The early post-attempt period is considered to be one of the most at-risk time windows for suicide reattempt or completion. Among the post-crisis prevention programmes developed to compensate for this risk, Brief Contact Interventions (BCIs) have been proven to be efficient but not equally for each subpopulation of attempters. Vigilans is a region-wide programme that relies on an algorithmic system to tailor surveillance and BCI provisions to individuals discharged from the hospital after a suicide attempt. Vigilans' main objective is to reduce suicide and suicide reattempt rates both at the individual level (patients included in Vigilans) and at the populational level (inhabitants of the Nord – Pas-de-Calais region).

**Intervention.** At discharge, every attempter coming from a participating centre is given a crisis card with an emergency number to contact in case of distress. Patients are then systematically recontacted 6 months later. An additional 10-day call is also given if the index suicide attempt is not the first one. Depending on the clinical evaluation during the phone call, the *Call Team* may carry out proportionated crisis interventions. Personalized postcards are sent whenever patients are unreachable by phone or in distress.

**Methods and analysis.** On the populational level, mean suicide and suicide attempt rates in Nord – Pas-de-Calais will be compared before and after the implementation of the programme. Here/there cross-sectional comparisons with a control region will test the spatial specificity of the observed fluctuations, while time-series analyses will be performed to corroborate the temporal plausibility of imputing these fluctuations to the implementation of the programme. On the individual level, patients entered in Vigilans will be prospectively compared to a matched control cohort by means of survival analyses (survival curve comparisons and Cox models).

**Ethics and dissemination.** Vigilans interventional components fall under the ordinary law care regime, and the individuals' general rights as patients apply with no addendums or restrictions for their participation in the programme. The research section received authorization from the Ethical Committee of Lille Nord-Ouest under the caption "Study aimed at evaluating routine care" and is registered in "Clinical Trials" under the number NCT03134885. The French Ministry of Health plans to extend the experimentation to other regions and probe the relevance of this type of "bottom-up" territorial prevention policy at the national level.

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**Strengths and limitations of this study**

- Complementary methods and indicators are used to comprehensively and exhaustively assess the multi-stage effects of the Vigilans program
- To better inform public health policies, primary efficacy analyses are performed at both the individual and populational levels
- An expected cohort of more than 10 000 suicide attempters will ensure strong statistical power and provide an unprecedented research database of suicide attempters

**Trial Registration**

The study was registered with the ClinicalTrials.gov registry; number: NCT03134885





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discharge. In Motto's "connectedness" framework, letters help disrupt isolation by allowing acquaintances to express positive feelings towards the patients and show that someone is caring for them;

- *Postcard mailings*. Instead of letters, Carter et al. suggested sending personalized postcards based on the same time-frame as Motto, i.e., at months 2, 3, 4, 5, 6, 8, 10 and 12 post-discharge (8);
- *Texting*. In line with the "connectedness" framework, the effectiveness of text message campaigns aimed at preserving the connection between attempters and healthcare systems is currently being tested in a French multicentre study (9).

In 2015, Milner et al. and Inagaki et al. simultaneously published two meta-analyses assessing the effect of BCIs on suicide attempters (10,11). Their converging conclusions suggested that patients benefitted from the recontact procedures, showing significantly lower relapse and suicide rates when compared to treated-as-usual controls. While Milner et al., whose meta-analysis included 3 studies and 3 549 patients, found that reattempts were 1.66 times less frequent in the BCI patients than in controls (IRR = 0.66, IC95%: 0.54-0.80) (10), Inagaki et al. calculated a similar BCI vs control IRR of 0.83 (IC95%: 0.71-0.97) (11).

The well-documented efficiency of BCI procedures, together with their low cost and ease of deployment (as compared with intensive follow-ups) are strong arguments that advocate for their integration in a large multi-level prevention strategy. In addition, because BCI have been shown to be differentially effective in subpopulations depending on patients' age, gender and self-harm history, a combination of BCIs would allow for effective and flexible implementation.

In 2011, we designed ALGOS, an algorithm that combined different types of BCIs into a single operational monitoring system. In brief, ALGOS was a post-discharge prevention programme that consisted of implementing contact and surveillance during the 6 months following a suicide attempt. The innovation lied in the modularity of the system, as settings were adapted to different subpopulations of suicide attempters:

- *Primary attempters* were handed a *Green Card* at discharge. If the patient subsequently called the card contact, the corresponding "emergency centre" carried out a careful clinical evaluation, which either lead to a proactive intervention or a scheduled appointment within 24 hours, depending on the suicide risk level.
- *Multiple attempters* were given a phone call between the 10<sup>th</sup> and 21<sup>st</sup> days post-discharge. Similarly, proactive interventions or within-24 h appointments were organized if the clinical team detected a high suicide risk. If the patients were unreachable or



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refused pro-active care, the ALGOS team sent them postcards, in line with Carter's protocol (8).

Notably, a brief report was sent to the patient's general practitioner (GP) and referring psychiatrist at admission and at each phone or in-person contact.

The ALGOS algorithm was evaluated by a multicentre randomized controlled trial (RCT) in 24 French facilities. In a per-protocol analysis that included 949 patients, we found the combined BCIs to be superior to each brief contact taken separately, with a 5.6% reduction in reattempt rate in comparison to the rate from the treatment-as-usual group ( $p = 0.024$ ) (12). In parallel, an independent team from the French Institute for Public Health Research (IRESP) conducted a qualitative survey on patients, GPs, psychiatrists, psychologists, emergency physicians and the ALGOS team to obtain a more in-depth understanding of how the system modified feelings and representations and to collect opinions about how to improve the system. Preliminary results suggested that ALGOS allowed for the preservation or restoration of a feeling of belongingness in patients. It also aroused interest and a willingness to collaborate in the GPs, who nevertheless asked for more efficient communications paths.

These results provided sufficiently solid arguments for the release and generalization of ALGOS as an open healthcare offer, while putting forward some improvement pathways for the algorithm. Regional funds were raised to upgrade and implement the system – re-named Vigilans – in the whole Nord – Pas-de-Calais region, a 4.3-million-inhabitant territory in the North of France. The Vigilans system and its evaluation protocol are presented here.

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### 2. Objectives

#### 2.1. Interventional goals

VigilanS follows the primary goals of reducing completed suicide and suicide reattempt rates among individuals who are released from the hospital after an index suicide attempt. From an integrative perspective, this main objective can be qualified as *distal*, as it is expected to result from the following converging intermediary (or *proximal*) objectives that the system intends to achieve:

- [a] To implement an adaptive recontact system that smoothly and effectively combines surveillance and different types of BCIs that fit each patient's specific needs;
- [b] To optimize the care management of patients discharged from the hospital after a suicide attempt by providing health stakeholders with standardized tools, effective skills and specialized literacy;
- [c] To offer professionals involved in the follow-up of suicide attempters a readily available alert network to improve their coordination and reactivity in case of new suicidal crises.

#### 2.2. Evaluative goals

Echoing its *distal* interventional objective, VigilanS' evaluation primarily aims at assessing the impact of the programme on suicide morbi-mortality. According to our hypothesis, implementation of VigilanS in the Nord – Pas-de-Calais will significantly reduce suicide and suicide reattempt rates not only in patients effectively included in the system but also in the whole population of the region.

A first line of secondary objectives consists of appraising the generalizability of the system and eliciting tracks for future improvement, namely the following:

- Measure the quality of the system's territorial deployment;
- Measure the level of its activation;
- Measure its acceptability.

A second line of secondary objectives was determined to specify the putative efficiency of the system through the following:

- Disclosing the consequences of its implementation for the patients' healthcare paths;
- Assessing its impact on the professionals' knowledge and representations about suicide;



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#### 3.2.1. Outgoing phone calls

Each call will allow for controlling the suicide risk status, checking on compliance with follow-up care and involving new health professionals when necessary.

After every call, a short report is sent to the patient's referral psychiatrist or GP.

At each contact, the *Call Team* members may still decide to send postcards whenever estimated to be beneficial for the patient or to programme another call within the patient's desired timeframe, especially if a crisis is going on. The phone crisis intervention can be repeated as many times as required within a period from a few hours to several days.

- **10-day calls**

When the index suicide attempt is not the first one, patients are called 10 to 20 days after their discharge. Actions subsequently taken mainly depend on the patient's suicide risk level:

- *In cases of immediate suicide risk*, the *Call Team* member (cf. Section 3.3 for description of the *Call Team*) collects minimum key information before referring the patient to an emergency practitioner, who in turn dispatches appropriate urgency aid (GP, ambulance or medicalized urgency vehicle).
- *In cases of moderate suicide risk*, the *Call Team* member conducts a thorough clinical evaluation and carries out a phone intervention accordingly. With the main aim of securing the patient and alleviating his/her distress, this intervention mostly consists of counselling and guidance. It can also include offering support to close relatives or soliciting assistance from a proximal health professional. In addition to this crisis intervention, 4 postcards are also sent within the following 5 months.
- *If there is no suicide risk and the patient complies with follow-up care*, any further action is judged unnecessary by default until the end of the monitoring.

Notably, if the patient remains unreachable despite 3 call attempts scheduled at different days and different times, the programme sends him/her 4 postcards within 5 months.

- **6-month calls**

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Every patient entering Vigilans is contacted by phone 6 months after inclusion in the programme. The general purpose of this call is to make a last clinical update before proposing to end the surveillance. However, the monitoring can be extended for an additional 6-month period whenever needed, either at the discretion of the *Call Team* or at the request of the patient. Similarly, if the subject is evaluated to be a high suicide risk, the *Call Team* may trigger the same actions as for the 10-day call.

The *6-month call* also has an evaluative value. The psychological assessment is structured around the administration of the Mini International Neuropsychiatric Interview (MINI DSM-5) (13) and the Columbia Suicide Severity Rating Scale (C-SSRS) (14). In addition, patients are invited to respond to an online satisfaction questionnaire.

3.2.2. Incoming phone calls

After having clarified the reasons why the patient is calling, the responder promptly carries out an evaluation of the level of the patient's suicidality. The ensuing interventional protocol is the same as for the *10-day call*: referral to an emergency practitioner if the risk is immediate, complete evaluation and crisis intervention if the risk is judged to be moderate, and no further action if the risk is estimated to be low.

3.2.3. Postcards

As stated above, the postcard-sending system may be activated either systematically when the patient is unreachable or upon the initiative of the *Call Team* whenever it is estimated that the patient is in trouble. The mailing is then scheduled monthly for a period of 4 months. Each of the postcard is personalized with the name of the patient and the logo and contact information of the unit from which he/she was discharged. Postcards are sealed in a neutral envelope with handwritten addresses. Patients may receive several batches of postcards if they reattempt suicide or if the monitoring is reset.

3.2.4. In case the patient reattempts suicide

In case another suicide attempt occurs during the monitoring period, the programme is reset for an additional 6-month period. If a patient attempts suicide more than 3 times within the year following his/her admission to the programme, the monitoring is deemed inefficient and stopped. The patient is then referred to another, more intensive healthcare programme, as agreed upon by the professional partners.

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### 3.3. Operational setting

The operational body of the system is split into 2 closely connected teams.

- The *Coordination Team* monitors the deployment of the programme, oversees the coordination with the *Partner Centres*, guarantees the timeliness of the interventions and supervises the follow-up of the patients. This team receives the notifications of inclusion and centralizes the data. The *Coordination Team* is also in charge of sending the postcards to the patients and the correspondence letters to their medical referees.
- The *Call Team* both carries out the phone BCIs and handles the incoming calls from distressed patients, in compliance with the pre-defined algorithm. This team is composed of 3 psychologists and 3 psychiatric nurses specially trained for suicidal crisis management and psychosocial interventions. The *Call Team* is entirely dedicated to quickly and directly establishing, maintaining or restoring the link with attempters or between attempters and caregivers. Efforts were made to develop an effective collaboration between Vigilans and medical emergency services. For this purpose, the Regional Emergency Medical Assistance Service (SAMU) of Lille agreed to host the *Call Team* in its dispatch centre, thus ensuring proximity and reactivity.

### 4. Evaluation: methods and analysis

We designed parallel research protocols to judge both the proximal and distal achievements of the programme. **Table 1** presents the correspondence between interventional objectives, evaluative goals, protocols, and judgement criteria. A summary of the timescales according to which we will collect data and carry out the analytical procedures can be found **Figure 3**.



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	Interventional goals	Evaluative goals	Indicators	Procedure
DISTAL (PRINCIPAL)	Reduce the rates of suicides and suicide reattempts in individuals discharged from hospital after an index suicide attempt	Assess the effects of the program in terms of reduction of suicide and suicide reattempt rates in Vigilans cohort	Suicide and suicide reattempt rates in the cohort  <i>Sources: monitoring, CapiDC, and PMSI</i>	Prospective comparison with a control cohort via survival analyses
		Assess the territorial effects of the program in terms of reduction of suicide and suicide reattempt rates in the Nord – Pas-de-Calais region	- Suicide and suicide reattempt rates in the Nord – Pas-de-Calais Region  <i>Sources: monitoring, CapiDC, and PMSI</i>	Longitudinal interrupted time-series analysis  Cross-sectional here/there comparisons with Picardie's data
PROXIMAL (SECONDARY)	Implement an effective BCIs and surveillance system	Measure the level of territorial implementation of the program	- Penetrance rate	Description
		Measure the functioning of the program in terms of BCIs provision	- Number of <i>Green Cards</i> distributed	Description
			- Number of outgoing calls - Number of postcard sent	
	Optimize the care management of patients discharged from hospital after a suicide attempt	Measure the acceptability of the program	- Professionals' opinion about the possibility to integrate the program in their practice	- Quantitative assessment: questionnaires
			- Patients' opinion about the efficiency and/or intrusiveness of the system	- Qualitative assessment: semi-structured interviews
				Descriptive analysis
	Optimize the care management of patients discharged from hospital after a suicide attempt	Disclose the effects of the program on the patients' healthcare paths	- Number of professionals involved in patients' management - Number of medical appointments - Use of medical treatments, - Number of admissions in a psychiatric facility  <i>Sources: PMSI</i>	Cross sectional comparisons 1 year before <i>versus</i> 1 year after the entry in the program
		Assess the impact of the program on the professionals' knowledge about suicide	- Knowledge of Suicide Scale score	Cross sectional comparison of the scores before <i>versus</i> 9 months after the opening of the <i>Partner Centers</i>

Table 1. Vigilans interventional goals, and evaluative goals and method

4.1. Evaluation of Vigilans' efficacy with respect to its primary objective

4.1.1. Judgement criteria



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VigilanS' perspective in terms of prevention encompasses both suicidal reattempts and suicide occurrences. Furthermore, thanks to its extensive territorial coverage, the programme expects to have effects not only on included patients but also on the general population of Nord – Pas-de-Calais. Consequently, the primary judgement criterion chosen to evaluate VigilanS' efficacy is composite and comprises suicide and suicide reattempt rates both in the VigilanS cohort and in the population of the Nord – Pas-de-Calais region.

#### 4.1.2. Databases

The French Epidemiology Center for Epidemiology on Medical Causes of Death (CépiDC) will provide the regional suicide mortality rates. Because French legislation does not authorize the unveiling of anonymity for such population databases, we cannot assess any associations with our cohort. Alternatively, the vital statuses of the patients included in the programme will be assessed *via* the *6-month call*. In cases of patients being lost to follow-up, official Civil Registers will be consulted. If the patient is subsequently found dead, the cause of death will be confirmed from the GP's report.

The rate of new suicide reattempts in the cohort will be derived from the follow-up assessment. The determination of the status of each participant regarding suicide reattempts will be achieved by cross-checking self-reports during phone calls, emergency registers and, if applicable, re-entries into the system. On a broader scale, the regional rates of suicide attempts and reattempts will be extracted from the Program for Medicalization of Information Systems (PMSI), a national register that records every admission, discharge and healthcare act in the French hospital system.

#### 4.1.3. Procedure and analysis

To assess any possible effects of VigilanS on suicide and suicide attempt rates, we decided to breakdown the analytical procedure into 2 levels.

First, the follow-up design will allow for the performance of prospective analysis on the individual level. Patients who benefitted from the BCIs and the surveillance system will be compared to a cohort of age and sex-matched attempters treated as usual. This control cohort will be randomly sampled from the emergency registers of Picardie, a region that adjoins Nord – Pas-de-Calais and has comparable suicide rates and sociodemographic characteristics (15). For each cohort, Kaplan-Meier survival curves will be computed, and the cumulative survival distributions will be compared between cohorts by a log-rank test. In

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addition, Cox regressions will provide the hazard risk of suicide or suicide reattempt that is associated with belonging to Vigilans vs belonging to the control cohort.

The second level of analysis will be populational. To evaluate the efficacy of Vigilans in the whole living area of Nord – Pas-de-Calais, we will compare mean suicide and suicide attempt rates *before* and *after* the launching of the programme (i.e., period 2013-2015 vs period 2016-2018). Two complementary analytical strategies will be carried out to test whether the observed trends are imputable to the implementation of the system. In the first step, interrupted time-series analyses will allow for the verification of the temporal coherence of the causality assumption, i.e., making sure that the observed fluctuations in suicide and suicide attempt rates significantly diverge from expected temporal trends. In the second step, we will test the spatial specificity of Vigilans' effects by comparing the mean suicide and suicide attempt rates of Nord – Pas-de-Calais (*here*) with those of Picardie (*there*) based on a repeated cross-sectional analysis (i.e., before and after the implementation of the programme).

4.2. Evaluation of Vigilans' efficacy with respect to its secondary objectives

- **To evaluate the deployment of the program**

The quality of Vigilans' deployment will be judged according to the following criteria:

[1] *Its level of territorial implementation*, as estimated by a "penetrance rate", calculated as the number of patients included in the programme divided by the overall number of admissions in the same period for the same indication. The latter figure, i.e., the number of patients admitted to the ED for a suicidal gesture but not subsequently hospitalized, will be locally accessed *via* the emergency team registers.

[2] *Its functioning*, i.e., the effectiveness of the system in terms of BCI provision. Indicators are the following:

- The number of *Green Cards* distributed. This is expected to be as important as the number of patients in the cohort.
- The number of outgoing calls. At 10 days, this should reach the number of patients with recurrent suicide attempts. By contrast, every patient will be attempted to be contacted by a *6-month call*, the number of which will thus reflect the attrition during the follow-up.
- The number of postcards sent. According to the algorithm, this is expected to be at least four times the number of unreachable patients.

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If the system ensures this minimum “routine” functioning, then the delivery of any surplus *Green Cards*, calls, or postcards will provide access to the amount of “unsystematic”, or “critical” interventions.

[3] *Its acceptability.* Acceptance by both patients and professionals is a key point when considering the generalizability of a system. In the specific case of Vigilans, acceptability will be defined, on one hand, by how patients subjectively appreciate the helpfulness and/or invasiveness of the programme and, on the other hand, by how collaborative caregivers incorporate it into their own practice. We will use two complementary methods to probe this issue:

- Quantitative appraisal. At the 6-month call, every patient will be asked to fulfil a short digital inquiry. Similarly, we will send every GP, psychiatrist and emergency worker an online or paper survey either at the end of the surveillance period or 9 months after the opening of their affiliate *Partner Centre*. Responses will undergo descriptive analyses.
- Qualitative appraisal. An independent experienced interviewer will conduct semi-structured qualitative interviews with representative samples of patients and professionals. Patients (n = 50) will be randomly selected from the whole admission list stratified by age, gender, history of suicide attempt and origin *Partner Centre*. Professionals (n = 50) will be randomly selected from all *Partner Centres*. A thematic content analysis will be applied to the narrative material extracted from the interviews.

To enable a continuous improvement dynamic, questionnaires and interviews will also serve to collect professionals’ and patients’ suggestions about how to optimize or correct the system.

- **To assess the efficacy of the programme in terms of healthcare optimization**

According to one of our interventional expectations, Vigilans will optimize the health path of suicide attempters by improving how the professionals cooperate to make health needs and offers match. For each patient, the health pathway will be compared between the year preceding and the year following entry in the programme based on relevant indicators extracted from the CNAM register (the French national health insurance system). Analysis will be conducted under 2 types of hypothesis. On one hand, we make the unilateral assumption that the number of professionals involved in the management of the patients will decrease towards the number of official referees (i.e., GP and/or psychiatrist) as the time to obtain a medical appointment with these referees in case of a crisis decreases. On the other

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hand, our hypothesis about the effects of Vigilans on the number of medical appointments, use of medical treatments, and number of admissions to a psychiatric facility will be two-tailed. This choice reflects the impossibility of determining *a priori* whether the programme will result in reduced care consumption because of general mental health improvements (i.e., reductions in care needs), if it will merely promote access to care (i.e., increases in care offers), or if it will do both.

One of the additional reasons why the system may enhance the care management of suicide is the collateral effect that we expect it to have on the professionals' suicide literacy. We indeed predict that Vigilans will convey a common theoretical basis and a shared language that will facilitate the cooperation between stakeholders. In the same line, we expect the programme to help them acquire new operational skills that they could apply in their future practice of suicidal crisis management. To test these assumptions, we built an ad hoc questionnaire inspired from Batterham's "Literacy of Suicide Scale" (16), named "Knowledge of Suicide Scale" (KSS). This questionnaire is designed to test general epidemiological knowledge, as well the extent to which participants endorse common misconceptions about suicide (e.g., "When one has decided to take one's life, nothing can be done to prevent the death"). The KSS will be administered to every healthcare professional in the *Partner Centres* who will potentially be in contact with suicidal patients. The total score for the questionnaire will be considered our judgement criterion for literacy improvement and, as such, will be compared before (at the *Partner Centre* opening) and after (9 months later) the implementation of the programme.

- **To measure the activation of the system**

In cases of distress, the patients or their referees can activate Vigilans by calling the *Green Card* phone number. Two proxies will be used to measure the degree of activation of the system, as well as its ability to respond accordingly with appropriate interventions:

- The number of incoming calls; and
- The proportion of incoming phone calls categorized by each type of intervention (phone contact schedule, referral to GP or psychiatrist, dispatch of an emergency team, etc.).

Both measurements will undergo descriptive analyses.

### 4.3. Characterization of responder vs non-responder profiles

Responder and non-responder profiles will be defined in reference to 2 main outcomes:

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- The individual compliance to the programme. A patient will be considered compliant whenever he/she is reachable at all outgoing calls (i.e., 6-month and 10-day calls);
- The individual efficiency of the programme. At the individual level, the programme will be judged efficient whenever the patient does not reattempt suicide or die by suicide.

To characterize responder profiles, we will perform multivariate logistic regressions to predict compliance and effectiveness status from several clinical variables, either collected at inclusion or during the 6-month call: sociodemographic characteristics, type and cause of the index suicide attempt, duration of the hospital stay at inclusion, presence of relatives at inclusion, psychopathological profile as assessed by the MINI lifetime, suicidality as assessed by the C-SSRS, number of subsequent suicide attempts within the follow-up period, number of emergency calls, and number of hospitalizations after the index suicide attempt.

---

PLEASE INSERT FIGURE 3 HERE

---

#### 4.4. Patient and Public Involvement

VigilanS is the release and generalization of ALGOS as an open healthcare offer.

The ALGOS algorithm was evaluated by an independent team from the French Institute for Public Health Research (IRESP) who conducted a qualitative survey on patients.

The development of the research was based on this qualitative survey of ALGOS study. This survey allowed to collect patient's opinions to improve the system according to these priorities, experiences and preferences.

There is no patient's involvement in the design of this study but it was assessed by an Ethic's committee (where patient's associations are presents).

The results will be disseminated to study participants per VigilanS website.

#### 4.1. Sample size calculations

We estimated the number of participants needed for sufficient statistical power in our inferential analyses as follows:

- According to the PMSI's most recent figures, suicide attempts accounted for 10,000 hospitalizations in 2014 in the Nord – Pas-de-Calais region. On this basis, we can expect

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approximately 20,000 patients during the two-year intervention phase. According to ALGOS data (13), the suicide reattempt rate is 12.8% among patients who are still in the care system 6 months after a suicide attempt. Ergo, the number of events is estimated to be 2,500.

To assess the main goal (profiles of people who did or did not attempt a first suicide), a multivariate logistic regression will be used. There is no consensus on a general formula to calculate the number of subjects in this environment. Guidelines are suggested for the number of minimum events for each variable inserted in a pattern (which we call events, the subjects of the smaller squad). According to Concato et al. (17), 10 to 20 events by variable are necessary. We plan to keep the number at 20.

With 2,500 events, it will be possible to analyse approximately 100 variables. The number of analysed variables (in view of suicide attempt modes and causes and of variables composing the MINI and C-SSRS) is estimated to be 50. Thus, this study should obtain a stable pattern of profiles.

**5. Ethics and dissemination**

Two components of Vigilans must be distinguished when considering the regulatory frameworks in which the programme fits.

- In regard to its interventional part (i.e., BCIs, surveillance and help provision), Vigilans falls under the ordinary law care regime. Consequently, the individuals' general rights as patients apply, with no addendums or restrictions for their participation in the programme, and no further consent is required. These statutory provisions are mentioned in the information letter that is provided to each patient at inclusion.
- Concerning its research section, Vigilans received an authorization from the Ethical Committee of Lille Nord-Ouest under the caption "Study aimed at evaluating routine care". In accordance with this legal status, the professionals that are included ensure the patient's compliance after complete oral and written information is given.

The dissemination of Vigilans in French territories is already underway. To test the generalizability of the system, the French Ministry of Health plans to replicate the experimentation in further regions with different sociodemographic characteristics: Brittany and Normandy (West & North of France), Languedoc Roussillon (South of France), Jura (Mountain region) and Martinique (French Caribbean Island). By reproducing and specifying the results of the present study, this extension is expected to provide arguments solid



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enough for the implementation of such a modular BCI/surveillance system on a nationwide scale. At the same time, the Ministry will have the opportunity to probe the relevance of Vigilans' implementation strategy – which is based on local collaborations and professional cooperation – in different populational and infrastructural conditions. If proven effective, this “bottom-up” strategy could inspire future targeted prevention policies from a more general public health perspective.

With respect to research, Vigilans is expected to bring considerable progresses by forming an unprecedented cohort of more than 10 000 suicide attempters. Beyond the understandings that such a database may produce about suicide attempts in general, it will certainly and more specifically help demonstrate the dynamic interactions between attempters and monitoring systems. As emphasized by Alice Milner (10), we need to go further in the monitoring process for the sake of prevention efficiency. This requires answering important questions that remain unsolved: what type of contact is best for which psychopathologic profile? Which adjustments are needed for borderline patients? Which adjustments are best for youths, prisoners and elderly patients? We are confident that Vigilans' evaluative study will provide some answers, as it has the complementary benefits of both quantitative and qualitative methods.

## 6. Funding

This work was supported by regional agency of health of Hauts de France and Conseil Regional of Nord Pas de Calais

## 7. Conflicts of interests

The authors declare that they have no competing interest from the publication of this manuscript

## 8. Author Contributions

All authors were responsible for the development of the study design.

GV and MW have conceived the algorithm. GV is responsible of the Vigilans system deployment.

SD, CEN, GV have been involved in writing up, revising and optimising the study protocol.

All authors have read and corrected the draft versions and all authors contributed to and approved the final manuscript.



**Legends**

Figure 1. Vigilans' territorial coverage in the Nord – Pas-de-Calais Region: inventory of the *Partner Centres*

Figure 2. Vigilans' algorithm for surveillance and Brief Contact Interventions provision

Figure 3. Data collection and evaluation timescales, as appraised through different levels of analysis. CS: completed suicide, SA: suicide attempt, KSS: Knowledge of Suicide Scale, MINI: Mini International Neuropsychiatric Interview, C-SSRS: Columbia Suicide Severity Rating Scale

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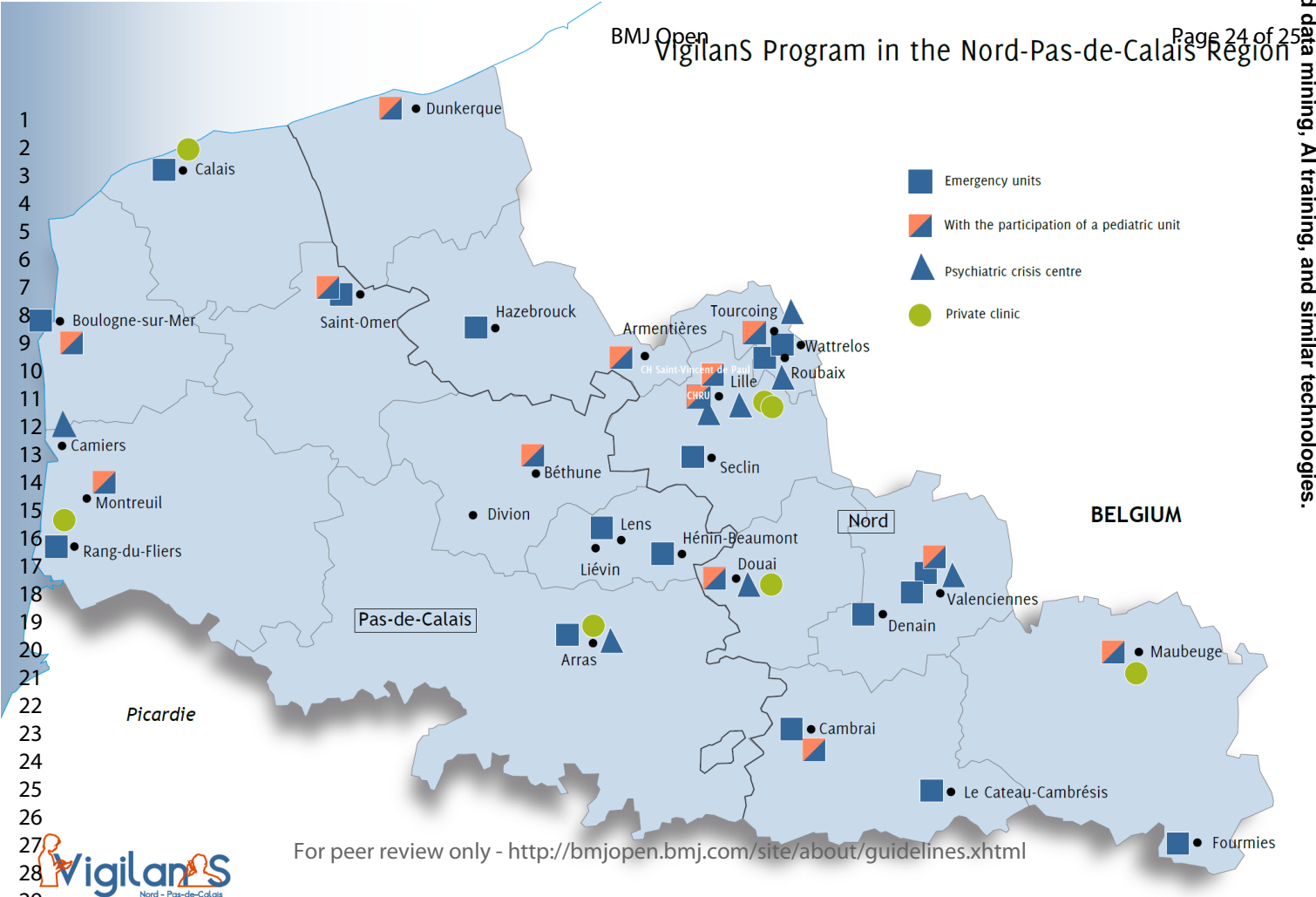
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## Vigilans Program in the Nord-Pas-de-Calais Region



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For any suicide attempter discharged from an in-patient or emergency unit of the region

## Day1

Upon discharge, the patient receives a Vigilans "crisis card" with a telephone number to be called whenever needed. Vigilans informs, by mail, the patient's general practitioner and/or psychiatrist that the patient has been placed under surveillance. At the same occasion, healthcare professionals are provided with the contact of a dedicated support hotline.



For suicide attempt repeaters

## Day10 to Day20

In case the current suicide attempt is not the first one, Vigilans contacts the patient between the 10th and 20th day after discharge.



The patient is notified by letter or SMS text before any contact. Vigilans sends a report to the patient's general practitioner and psychiatrist.

Ordinary phone call

Unreachable or in psychological difficulty : postcards are mailed (1 monthly for 4 months)

Suicidal crisis : emergency consultation



+/- scheduling a follow-up phone call if needed

## At 6 months

For all suicide attempters



VigilanS contacts the patient by telephone

The patient is notified by letter or SMS text before any contact. Vigilans sends a report to the patient's general practitioner and psychiatrist.

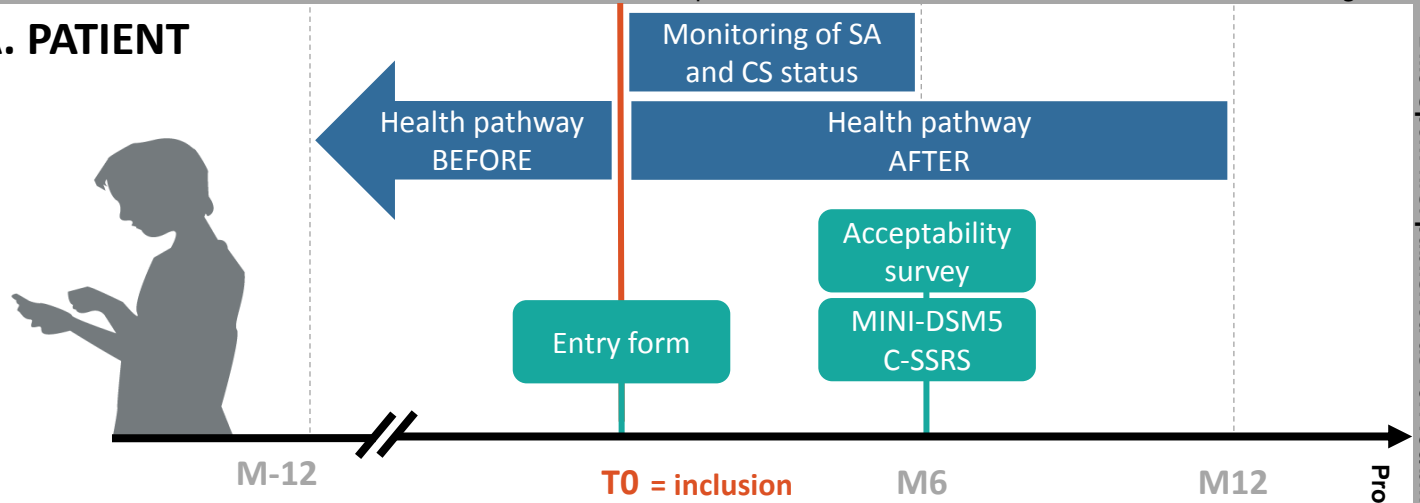
Upon recurrence of a suicide attempt, the patient is put back in the surveillance program for another 6 months.

Surveillance stops if the crisis situation has sufficiently improved,

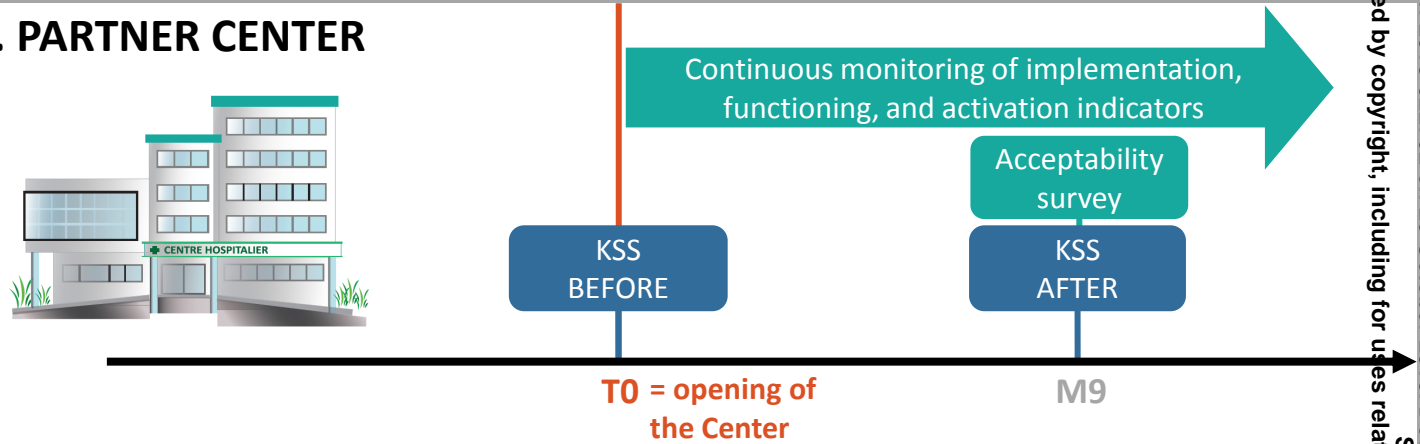
but <http://bmjopen.bmj.com/site/about/guidelines.xhtml>

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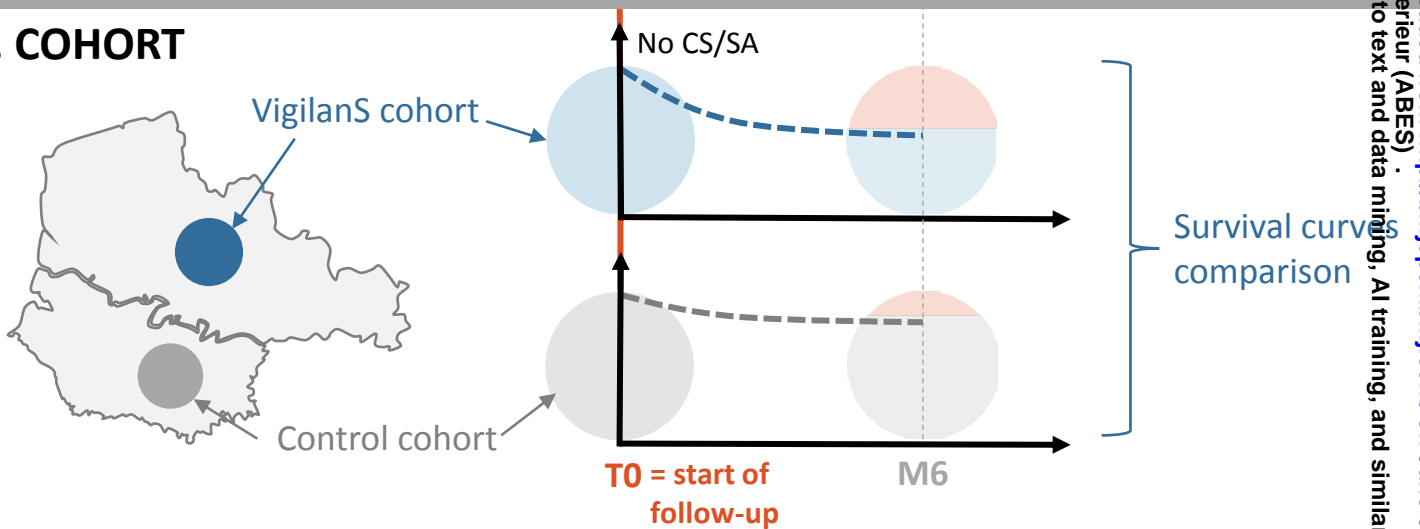
## A. PATIENT



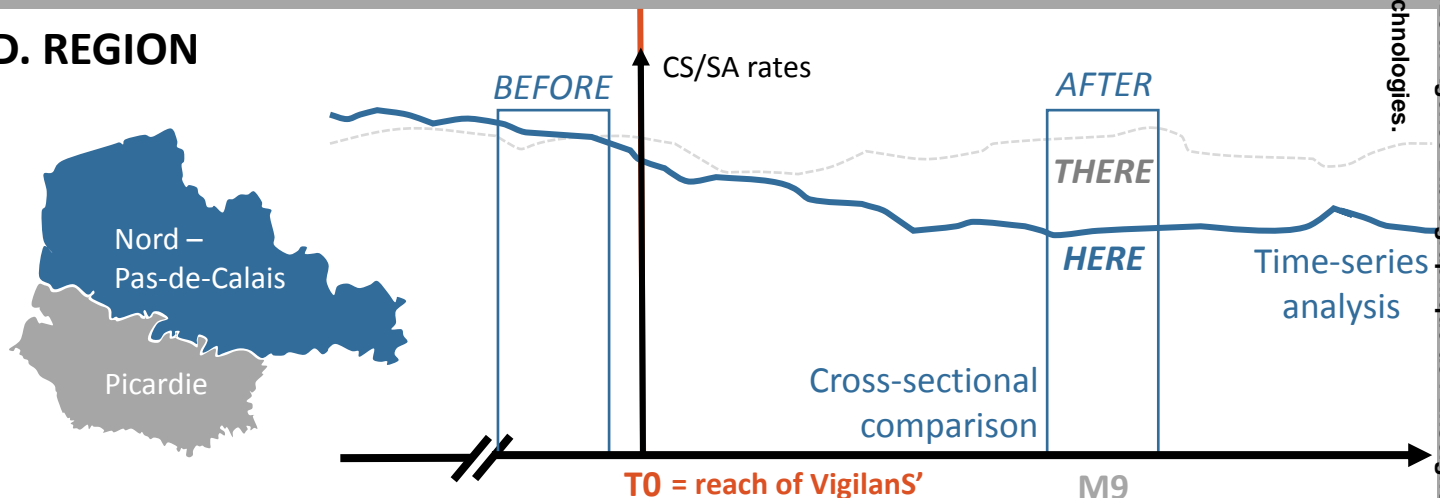
## B. PARTNER CENTER



## C. COHORT



## D. REGION



## COMBINING BRIEF CONTACT INTERVENTIONS (BCI) INTO A DECISION MAKING ALGORITHM TO REDUCE SUICIDE REATTEMPT: THE VIGILANS STUDY PROTOCOL.

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2018-022762.R1
Article Type:	Protocol
Date Submitted by the Author:	07-Jun-2018
Complete List of Authors:	Duhem, Stephane; CHU de Lille, Univ. Lille, Inserm, CIC1403 Clinical Investigation Center, F-59000 Lille, France; CHU Lille, Department of Psychiatry and Forensic Medicine, F-59000 Lille, France Berrouguet, Sofian ; Brest Medical University Hospital at Bohars, Debien, christophe; CHU Lille, Department of Psychiatry and Forensic Medicine, F-59000 Lille, France DUCROCQ, Francois; CHRU DE LILLE, PSYCHIATRY Demarty, Anne-Laure; CHU de Lille, Univ. Lille, Inserm, CIC1403 Clinical Investigation Center, F-59000 Lille, France LILLE, FR Messiah, Antoine; INSERM, U-669 "Mental Health and Public Health"; University of Miami School of Medicine, Public Health Sciences Courtet, Philippe; CHU Montpellier, Department of Psychiatry and Medical Psychology, F-34000 Montpellier Jehel, Louis; CHU Martinique, Department of Psychiatry, F-97200 Fort de France Thomas, Pierre; CHU Lille, Department of Psychiatry and Forensic Medicine, F-59000 Lille, France; Regional Federation for Research on Mental Health and Psychiatry, Hauts-de-France, F-59000 Lille Deplanque, Dominique; CHU de Lille, Univ. Lille, Inserm, CHU Lille, CIC1403 Clinical Investigation Center, F-59000 Lille, France LILLE, FR Danel, Thierry; Regional Federation for Research on Mental Health and Psychiatry, Hauts-de-France, F-59000 Lille WALTER, Michel; CHU Brest Notredame, Charles-Edouard; Centre Hospitalier Regional Universitaire de Lille, Psychiatry VAIVA, Guillaume; CHU Lille, Department of Psychiatry and Forensic Medicine, F-59000 Lille, France; SCALab Laboratory, CNRS-UMR 9193, F-59000 Lille
<b>Primary Subject Heading</b>:	Mental health
Secondary Subject Heading:	Public health
Keywords:	prevention, Suicide & self-harm < PSYCHIATRY, crisis management, organization of healthcare, Telemedicine < BIOTECHNOLOGY & BIOINFORMATICS



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COMBINING BRIEF CONTACT INTERVENTIONS (BCI) INTO A DECISION MAKING ALGORITHM TO  
REDUCE SUICIDE REATTEMPT: THE VIGILANS STUDY PROTOCOL.

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**Number of figures:** 3

**Number of tables:** 1

**Word count:** 4813

**Keywords:** prevention, suicide, crisis management, organization of healthcare, telemedicine, emergencies

**Abstract**

**Introduction.** The early post-attempt period is considered to be one of the most at-risk time windows for suicide reattempt or completion. Among the post-crisis prevention programmes developed to compensate for this risk, Brief Contact Interventions (BCIs) have been proven to be efficient but not equally for each subpopulation of attempters. Vigilans is a region-wide programme that relies on an algorithmic system to tailor surveillance and BCI provisions to individuals discharged from the hospital after a suicide attempt.

**Aim:** Vigilans' main objective is to reduce suicide and suicide reattempt rates both at the individual level (patients included in Vigilans) and at the populational level (inhabitants of the Nord – Pas-de-Calais region).

**Methods and analysis.** At discharge, every attempter coming from a participating centre is given a crisis card with an emergency number to contact in case of distress. Patients are then systematically recontacted 6 months later. An additional 10-day call is also given if the index suicide attempt is not the first one. Depending on the clinical evaluation during the phone call, the *Call Team* may carry out proportionated crisis interventions. Personalized postcards are sent whenever patients are unreachable by phone or in distress. On the populational level, mean suicide and suicide attempt rates in Nord – Pas-de-Calais will be compared before and after the implementation of the programme. Here/there cross-sectional comparisons with a control region will test the spatial specificity of the observed fluctuations, while time-series analyses will be performed to corroborate the temporal plausibility of imputing these fluctuations to the implementation of the programme. On the individual level, patients entered in Vigilans will be prospectively compared to a matched control cohort by means of survival analyses (survival curve comparisons and Cox models).

**Discussion:** Vigilans interventional components fall under the ordinary law care regime, and the individuals' general rights as patients apply with no addendums or restrictions for their participation in the programme. The research section received authorization from the Ethical Committee of Lille Nord-Ouest under the caption "Study aimed at evaluating routine care" and is registered in "Clinical Trials" under the number NCT03134885. The French Ministry of Health plans to extend the experimentation to other regions and probe the relevance of this type of "bottom-up" territorial prevention policy at the national level.

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**Strengths and limitations of this study**

- Complementary methods and indicators are used to comprehensively and exhaustively assess the multi-stage effects of the Vigilans program
  - To better inform public health policies, primary efficacy analyses are performed at both the individual and populational levels
  - An expected cohort of more than 10 000 suicide attempters will ensure strong statistical power and provide an unprecedented research database of suicide attempters
- the heterogeneity of suicide follow up strategies existing in participating centers are challenging issues. However, we believe that this naturalistic setting will bring critical insight to future suicide prevention guidelines.

**Trial Registration**

The study was registered with the ClinicalTrials.gov registry; number: NCT03134885



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- *Postcard mailings.* Instead of letters, Carter et al. suggested sending personalized postcards based on the same time-frame as Motto, i.e., at months 2, 3, 4, 5, 6, 8, 10 and 12 post-discharge (8);
- *Texting.* In line with the “connectedness” framework, the effectiveness of text message campaigns aimed at preserving the connection between attempters and healthcare systems is currently being tested in a French multicentre study (9).

In 2015, Milner et al. and Inagaki et al. simultaneously published two meta-analyses assessing the effect of BCIs on suicide attempters (10,11). Their converging conclusions suggested that patients benefitted from the recontact procedures, showing significantly lower relapse and suicide rates when compared to treated-as-usual controls. While Milner et al., whose meta-analysis included 3 studies and 3 549 patients, found that reattempts rate in the BCI patients were 0.66 times the reattempt rate of controls (IC95%: 0.54-0.80) (10), Inagaki et al. calculated a similar BCI vs control IRR of 0.83 (IC95%: 0.71-0.97) (11).

The well-documented efficiency of BCI procedures, together with their low cost and ease of deployment (as compared with intensive follow-ups) are strong arguments that advocate for their integration in a large multi-level prevention strategy. In addition, because BCI have been shown to be differentially effective in subpopulations depending on patients' age, gender and self-harm history, a combination of BCIs would allow for effective and flexible implementation.

In 2011, we designed ALGOS, an algorithm that combined different types of BCIs into a single operational monitoring system. In brief, ALGOS was a post-discharge prevention programme that consisted of implementing contact and surveillance during the 6 months following a suicide attempt. The innovation lied in the modularity of the system, as settings were adapted to different subpopulations of suicide attempters:

- *Primary attempters* were handed a *Crisis Card* at discharge. If the patient subsequently called the card contact, the corresponding “emergency centre” carried out a careful clinical evaluation, which either lead to a proactive intervention or a scheduled appointment within 24 hours, depending on the suicide risk level.
- *Multiple attempters* were given a phone call between the 10<sup>th</sup> and 21<sup>st</sup> days post-discharge. Similarly, proactive interventions or within-24 h appointments were organized if the clinical team detected a high suicide risk. If the patients were unreachable or refused pro-active care, the ALGOS team sent them postcards, in line with Carter's protocol (8).

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Notably, a brief report was sent to the patient's general practitioner (GP) and referring psychiatrist at admission and at each phone or in-person contact.

The ALGOS algorithm was evaluated by a multicentre randomized controlled trial (RCT) in 24 French facilities. In a per-protocol analysis that included 949 patients, we found the combined BCIs to be superior to each brief contact taken separately, with a 5.6% reduction in reattempt rate in comparison to the rate from the treatment-as-usual group ( $p = 0.024$ ) (12). We found no significant superiority of ALGOS in terms of death by suicide, probably due to a lack of statistical power related to the rarity of the event (3 suicides in the ALGOS group vs 8 suicides in the control group). In parallel, an independent team from the French Institute for Public Health Research (IRESP) conducted a qualitative survey on patients, GPs, psychiatrists, psychologists, emergency physicians and the ALGOS team to obtain a more in-depth understanding of how the system modified feelings and representations and to collect opinions about how to improve the system. Preliminary results suggested that ALGOS allowed for the preservation or restoration of a feeling of belongingness in patients. It also aroused interest and a willingness to collaborate in the GPs, who nevertheless asked for more efficient communications paths.

These results provided sufficiently solid arguments for the release and generalization of ALGOS as an open healthcare offer, while putting forward some improvement pathways for the algorithm. Regional funds were raised to upgrade and implement the system – re-named Vigilans – in the whole Nord – Pas-de-Calais region, a 4.3-million-inhabitant territory in the North of France. The Vigilans system and its evaluation protocol are presented here.



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## Study protocol

## 2. Objectives

### 2.1. Interventional goals

VigilanS follows the primary goals of reducing completed suicide and suicide reattempt rates among individuals who are released from the hospital after an index suicide attempt. From an integrative perspective, this main objective can be qualified as *distal*, as it is expected to result from the following converging intermediary (or *proximal*) objectives that the system intends to achieve:

- [a] To implement an adaptive recontact system that smoothly and effectively combines surveillance and different types of BCIs that fit each patient's specific needs;
- [b] To optimize the care management of patients discharged from the hospital after a suicide attempt by providing health stakeholders with standardized tools, effective skills and specialized literacy;
- [c] To offer professionals involved in the follow-up of suicide attempters a readily available alert network to improve their coordination and reactivity in case of new suicidal crises.

### 2.2. Evaluative goals

Echoing its *distal* interventional objective, VigilanS' evaluation primarily aims at assessing the impact of the programme on suicide morbi-mortality. According to our hypothesis, implementation of VigilanS in the Nord – Pas-de-Calais will significantly reduce suicide and suicide reattempt rates not only in patients effectively included in the system but also in the whole population of the region.

A first line of secondary objectives consists of appraising the generalizability of the system and eliciting tracks for future improvement, namely the following:

- Measure the quality of the system's territorial deployment;
- Measure the level of its activation;
- Measure its acceptability;
- Measure its medico economic sustainability.

A second line of secondary objectives was determined to specify the putative efficiency of the system, i.e.:

- Disclosing the consequences of its implementation for the patients' healthcare paths;
- Assessing its impact on the professionals' knowledge and representations about suicide;

- Characterizing the profile of attempters who positively respond to the programme in terms of compliance and efficacy.

### 3. Vigilans surveillance and BCI system

#### 3.1. Admission procedure

The gateway facilities of the system are referred to as *Partner Centres*. *Partner Centres* are medical units that are likely to receive suicidal individuals (emergency departments [ED], psychiatry crisis centres, psychiatry departments and private clinics) and agree to refer every discharged attempter to the programme. To ensure satisfactory territorial coverage, Vigilans recruited each of the 28 *Centres* of the Nord – Pas-de-Calais region (see [Figure 1](#)).

---

PLEASE INSERT FIGURE 1 HERE

---

It is important to note that Vigilans is to be statutory considered an ordinary care regime. Any individual leaving a *Partner Centre* after a suicide attempt is proposed to enter the system without restriction. Enrolment is formalized by the delivery of both a *Crisis Card* stating a unique toll-free phone number and an information letter about the programme.

Immediately after discharge, the *Partner Centre* is then asked to send a brief report to Vigilans with basic socio-demographic information about the patient, the name of his/her GP or referring psychiatrist, and some contextual elements related to his/her hospitalization (reported causes of the suicidal attempt, date of discharge, follow-up care, etc.). Upon receipt of the medical note, Vigilans sends a letter to the GP with the notification that the patient has entered the programme.

#### 3.2. The algorithm

The surveillance and BCI algorithm is presented [Figure 2](#). The algorithm combines in a customized way outgoing and incoming calls, postcard mailings, contact with medical referees and crises interventions.

---

PLEASE INSERT FIGURE 2 HERE

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#### 3.2.1. Outgoing phone calls

Each call will allow for controlling the suicide risk status, checking on compliance with follow-up care and involving new health professionals when necessary. After every call, a short report is sent to the patient's referral psychiatrist or GP. At each contact, the *Call Team* members may still decide to send postcards whenever estimated to be beneficial for the patient, or to program another call within the patient's desired timeframe. The phone crisis intervention can be repeated as many times as required within a period from a few hours to several days.

- **10-day calls**

When the index suicide attempt is not the first one, patients are called 10 to 20 days after their discharge. Actions subsequently taken mainly depend on the patient's suicide risk level:

- *In cases of immediate suicide risk*, the *Call Team* member (cf. Section 3.3 for description of the *Call Team*) collects minimum key information before referring the patient to an emergency practitioner, who in turn dispatches appropriate urgency aid (GP, ambulance or medicalized urgency vehicle).
- *In cases of moderate suicide risk*, the *Call Team* member conducts a thorough clinical evaluation and carries out a phone intervention accordingly. With the main aim of securing the patient and alleviating his/her distress, this intervention mostly consists of counselling and guidance. It can also include offering support to close relatives or soliciting assistance from a proximal health professional. In addition to this crisis intervention, 4 postcards are sent within the following 5 months.
- *If there is no suicide risk and the patient complies with follow-up care*, any further action is judged unnecessary by default until the end of the monitoring.

Notably, if the patient remains unreachable despite 3 call attempts scheduled at different days and different times, the programme sends him/her 4 postcards within 5 months.

- **6-month calls**

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Every patient entering Vigilans is contacted by phone 6 months after inclusion in the programme. The general purpose of this call is to make a last clinical update before proposing to end the surveillance. However, the monitoring can be extended for an additional 6-month period whenever needed, either at the discretion of the *Call Team* or at the request of the patient. Similarly, if the subject is evaluated to be a high suicide risk, the *Call Team* may trigger the same actions as for the 10-day call.

The *6-month call* also has an evaluative value. The psychological assessment is structured around the administration of the Mini International Neuropsychiatric Interview (MINI DSM-5) (13) and the Columbia Suicide Severity Rating Scale (C-SSRS) (14). In addition, patients are invited to respond to an online satisfaction questionnaire.

3.2.2. Incoming phone calls

After having clarified the reasons why the patient is calling, the responder promptly carries out an evaluation of the level of the patient's suicidality. The ensuing interventional protocol is the same as for the *10-day call*: referral to an emergency practitioner if the risk is immediate, complete evaluation and crisis intervention if the risk is judged to be moderate, and no further action if the risk is estimated to be low.

3.2.3. Postcards

As stated above, the postcard-sending system may be activated either systematically when the patient is unreachable or upon the initiative of the *Call Team* whenever it is estimated that the patient is in trouble. The mailing is then scheduled monthly for a period of 4 months. Each of the postcard is personalized. The recto consists of a figurative or abstract picture that is chosen in accordance with the patients' sociodemographic characteristics. On the verso, a short message signed on the behalf of the practitioner who initially met the patient expresses care wishes. The logo and contact information of the unit from which the patient was discharged also appears. Postcards are sealed in a neutral envelope with handwritten addresses. Patients may receive several batches of postcards if they reattempt suicide or if the monitoring is reset.

3.2.4. In case the patient reattempts suicide

In case another suicide attempt occurs during the monitoring period, the programme is reset for an additional 6-month period. If a patient attempts suicide more than 3 times within the

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year following his/her admission to the programme, the monitoring is deemed inefficient and stopped. The patient is then referred to another, more intensive healthcare programme, as agreed upon by the professional partners.

### 3.3. Operational setting

The operational body of the system is split into 2 closely connected teams.

- The *Coordination Team* monitors the deployment of the programme, oversees the coordination with the *Partner Centres*, guarantees the timeliness of the interventions and supervises the follow-up of the patients. This team receives the notifications of inclusion and centralizes the data. The *Coordination Team* is also in charge of sending the postcards to the patients and the correspondence letters to their medical referees.
- The *Call Team* both carries out the phone BCIs and handles the incoming calls from distressed patients, in compliance with the pre-defined algorithm. This team is composed of 3 psychologists and 3 psychiatric nurses specially trained for suicidal crisis management and psychosocial interventions. The *Call Team* is entirely dedicated to quickly and directly establishing, maintaining or restoring the link with attempters or between attempters and caregivers. Efforts were made to develop an effective collaboration between Vigilans and medical emergency services. For this purpose, the Regional Emergency Medical Assistance Service (SAMU) of Lille agreed to host the *Call Team* in its dispatch centre, thus ensuring proximity and reactivity.

## 4. Evaluation: methods and analysis

We designed parallel research protocols to judge both the proximal and distal achievements of the programme. **Table 1** presents the correspondence between interventional objectives, evaluative goals, protocols, and judgement criteria.

	Interventional goals	Evaluative goals	Indicators	Procedure
DISTAL	Reduce the rates of suicides and suicide reattempts in individuals discharged from hospital after an index suicide attempt	Assess the effects of the program in terms of reduction of suicide and suicide reattempt rates in Vigilans cohort	- Suicide and suicide reattempt rates in the cohort  <i>Sources: monitoring, CapiDC and PMSI</i>	Prospective comparison with a control cohort via survival analyses
		Assess the territorial effects of the program in terms of	- Suicide and suicide reattempt rates in the Nord-	Longitudinal interrupted time-

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		reduction of suicide and suicide reattempt rates in the Nord-Pas-de-Calais region	Pas-de-Calais region	series analysis Cross-sectional here/there comparisons with Picardie's region data
			<i>Sources: monitoring, CapiDC and PMSI</i>	
PROXIMAL (SECONDARY)	Implement an effective BCIs and surveillance system	Measure the level of territorial implementation of the program	- Penetrance rate	Description
		Measure the functioning of the program in terms of BCIs provision	- Number of Green Cards distributed	Description
			- Number of outcoming calls	
			- Number of postcard sent	
		Measure the acceptability of the program	- Professionals' opinion about the possibility to integrate the program in their practice	Quantitative assessment: questionnaires
			- Patients' opinion about the efficiency and/or intrusiveness of the system	Qualitative assessment: semi-structured interviews
				Descriptive analysis
	Optimize the care management of patients discharged from hospital after a suicide attempt	Disclose the effects of the program on the patients' healthcare paths	- Number of professionals involved in patients' management	Cross sectional comparisons 1 year before versus 1 year after the entry in the program
			- Number of medical appointments	
			- Use of medical treatments	
			- Number of admissions in a psychiatric facility	
			<i>Sources: PMSI</i>	
		Assess the impact of the program on the professionals' knowledge about suicide	- Knowledge of Suicide Scale score	Cross sectional comparison of the scores before versus 9 months after the opening of the Partner Centers

Table 1. VigilanS interventional goals, and evaluative goals and method

A summary of the timescales according to which we will collect data and carry out the analytical procedures can be found [Figure 3](#).

4.1. Evaluation of VigilanS' efficacy with respect to its primary objective

4.1.1. Judgement criteria

VigilanS' perspective in terms of prevention encompasses both suicidal reattempts and suicide occurrences. Furthermore, thanks to its extensive territorial coverage, the programme



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expects to have effects not only on included patients but also on the general population of Nord – Pas-de-Calais. Consequently, the primary judgement criterion chosen to evaluate Vigilans' efficacy is composite and comprises suicide and suicide reattempt rates both in the Vigilans cohort and in the population of the Nord – Pas-de-Calais region.

#### 4.1.2. Databases

The French Center for Epidemiology on Medical Causes of Death (CépiDC) will provide the regional suicide mortality rates. Because French legislation does not authorize the unveiling of anonymity for such population databases, we cannot assess any associations with our cohort. Alternatively, the vital statuses of the patients included in the programme will be assessed *via* the 6-month call. In cases of patients being lost to follow-up, official Civil Registers will be consulted. If the patient is subsequently found dead, the cause of death will be confirmed from the GP's report.

The rate of new suicide reattempts in the cohort will be derived from the follow-up assessment. The determination of the status of each participant regarding suicide reattempts will be achieved by cross-checking self-reports during phone calls, emergency registers and, if applicable, re-entries into the system. On a broader scale, the regional rates of suicide attempts and reattempts will be extracted from the Program for Medicalization of Information Systems (PMSI), a national register that records every admission, discharge and healthcare act in the French hospital system.

#### 4.1.3. Procedure and analysis

To assess any possible effects of Vigilans on suicide and suicide attempt rates, we decided to breakdown the analytical procedure into 2 levels.

First, the follow-up design will allow for the performance of prospective analysis on the individual level. Patients who benefitted from the BCIs and the surveillance system will be compared to a cohort of age and sex-matched attempters treated as usual. This control cohort will be randomly sampled from the emergency registers of Picardie, a region that adjoins Nord – Pas-de-Calais and has comparable suicide rates and sociodemographic characteristics (15). For each cohort, Kaplan-Meier survival curves will be computed, and the cumulative survival distributions will be compared between cohorts by a log-rank test. In addition, Cox regressions will provide the hazard risk of suicide or suicide reattempt that is associated with belonging to Vigilans vs belonging to the control cohort.



The second level of analysis will be populational. To evaluate the efficacy of Vigilans in the whole living area of Nord – Pas-de-Calais, we will compare mean suicide and suicide attempt rates *before* and *after* the launching of the programme (i.e., period 2013-2015 vs period 2016-2018). Two complementary analytical strategies will be carried out to test whether the observed trends are imputable to the implementation of the system. In the first step, interrupted time-series analyses will allow for the verification of the temporal coherence of the causality assumption, i.e., making sure that the observed fluctuations in suicide and suicide attempt rates significantly diverge from expected temporal trends. In the second step, we will test the spatial specificity of Vigilans' effects by comparing the mean suicide and suicide attempt rates of Nord – Pas-de-Calais (*here*) with those of Picardie (*there*) based on a repeated cross-sectional analysis (i.e., before and after the implementation of the programme).

#### 4.2. Evaluation of Vigilans' efficacy with respect to its secondary objectives

- **To evaluate the deployment of the program**

The quality of Vigilans' deployment will be judged according to the following criteria:

[1] *Its level of territorial implementation*, as estimated by a "penetrance rate", calculated as the number of patients included in the programme divided by the overall number of admissions in the same period for the same indication.

[2] *Its functioning*, i.e., the effectiveness of the system in terms of BCI provision. Indicators are the following:

- The number of Crisis *Cards* distributed.
- The number of outgoing calls. At 10 days, this should reach the number of patients with recurrent suicide attempts. By contrast, every patient will be attempted to be contacted by a *6-month call*, the number of which will thus reflect the attrition during the follow-up.
- The number of postcards sent.

If the system ensures this minimum "routine" functioning, then the delivery of any surplus *Green Cards*, calls, or postcards will provide access to the amount of "unsystematic", or "critical" interventions.

[3] *Its acceptability*. Acceptance by both patients and professionals is a key point when considering the generalizability of a system. In the specific case of Vigilans, acceptability will

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be defined, on one hand, by how patients subjectively appreciate the helpfulness and/or invasiveness of the programme and, on the other hand, by how collaborative caregivers incorporate it into their own practice. We will use two complementary methods to probe this issue:

- Quantitative appraisal. At the 6-month call, every patient will be asked to fulfil a short digital inquiry. Similarly, we will send every GP, psychiatrist and emergency worker an online or paper survey either at the end of the surveillance period or 9 months after the opening of their affiliate *Partner Centre*.
- Qualitative appraisal. An independent experienced interviewer will conduct semi-structured qualitative interviews with representative samples of patients and professionals. Patients (n = 50) will be randomly selected from the whole admission list stratified by age, gender, history of suicide attempt and origin *Partner Centre*. Professionals (n = 50) will be randomly selected from all *Partner Centres*.

To enable a continuous improvement dynamic, questionnaires and interviews will also serve to collect professionals' and patients' suggestions about how to optimize or correct the system.

[4] *Its medico-economic viability*. Even if Vigilans if proven efficient, an important question will remain as to whether the gain in terms of number of prevented suicides and suicide attempts is rationally proportionated to the expenses incurred for the algorithm. To answer this issue, we will conduct a two-steps medico-economic assessment of the program. First a micro-costing procedure will allow for performing a cost-effectiveness study. The costs of all the components of the algorithm taken separately, as well as their combination, will be proportionated to the number of avoided attempts and deaths, and compared to the as-usual treatment. Second, a cost-benefit analysis will complete the cost-effectiveness study by estimating the direct and indirect costs of the prevented suicides and suicide attempts in terms of consumption of care and medical goods and loss of productivity.

- **To assess the efficacy of the programme in terms of healthcare optimization**

According to one of our interventional expectations, Vigilans will optimize the health path of suicide attempters by improving how the professionals cooperate to make health needs and offers match. For each patient, the health pathway will be compared between the year preceding and the year following entry in the programme based on relevant indicators extracted from the CNAM register (the French national health insurance system).

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- **To measure the activation of the system**

In cases of distress, the patients or their referees can activate Vigilans by calling the *Crisis Card* phone number. Two proxies will be used to measure the degree of activation of the system, as well as its ability to respond accordingly with appropriate interventions:

- The number of incoming calls;
- The proportion of incoming phone calls categorized by each type of intervention (phone contact schedule, referral to GP or psychiatrist, dispatch of an emergency team, etc.).

4.3. Characterization of responder vs non-responder profiles

To characterize responder profiles, we will perform multivariate logistic regressions to predict the patients' compliance and response to the program from several clinical variables, either collected at inclusion or during the *6-month call*: sociodemographic characteristics, type and cause of the index suicide attempt, duration of the hospital stay at inclusion, presence of relatives at inclusion, psychopathological profile as assessed by the MINI lifetime, suicidality as assessed by the C-SSRS, number of subsequent suicide attempts within the follow-up period, number of emergency calls, and number of hospitalizations after the index suicide attempt.

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PLEASE INSERT FIGURE 3 HERE

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4.4 Patient and Public Involvement

Vigilans is the release and generalization of ALGOS as an open healthcare offer. The ALGOS algorithm was evaluated by an independent team from the French Institute for Public Health Research (IRESP) who conducted a qualitative survey on patients. The development of the research was based on this qualitative survey of ALGOS study. This survey allowed to collect patient's opinions to improve the system according to these priorities, experiences and preferences. There is no patient's involvement in the design of this study but it was assessed by an Ethic's committee (where patient's associations are presents) The results will be disseminated to study participants per Vigilans website

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## 5. Ethics and dissemination

Two components of Vigilans must be distinguished when considering the regulatory frameworks in which the programme fits.

- In regard to its interventional part (i.e., BCIs, surveillance and help provision), Vigilans falls under the ordinary law care regime. Consequently, the individuals' general rights as patients apply, with no addendums or restrictions for their participation in the programme, and no further consent is required. These statutory provisions are mentioned in the information letter that is provided to each patient at inclusion.
- Concerning its research section, Vigilans received an authorization from the Ethical Committee of Lille Nord-Ouest under the caption "Study aimed at evaluating routine care". In accordance with this legal status, the professionals that are included ensure the patient's compliance after complete oral and written information is given.

The dissemination of Vigilans in French territories is already underway. To test the generalizability of the system, the French Ministry of Health plans to replicate the experimentation in further regions with different sociodemographic characteristics: Brittany and Normandy (West & North of France), Languedoc Roussillon (South of France), Jura (Mountain region) and Martinique (French Caribbean Island). By reproducing and specifying the results of the present study, this extension is expected to provide arguments solid enough for the implementation of such a modular BCI/surveillance system on a nationwide scale. At the same time, the Ministry will have the opportunity to probe the relevance of Vigilans' implementation strategy – which is based on local collaborations and professional cooperation – in different populational and infrastructural conditions. If proven effective, this "bottom-up" strategy could inspire future targeted prevention policies from a more general public health perspective.

With respect to research, Vigilans is expected to bring considerable progresses by forming an unprecedented cohort of more than 10 000 suicide attempters. Beyond the understandings that such a database may produce about suicide attempts in general, it will certainly and more specifically help demonstrate the dynamic interactions between attempters and monitoring systems. As emphasized by Alice Milner (10), we need to go further in the monitoring process for the sake of prevention efficiency. This requires answering important questions that remain unsolved: what type of contact is best for which psychopathologic profile? Which adjustments are needed for patients suffering from personality disorders ? Which adjustments are best for youths, prisoners and elderly

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patients? We are confident that Vigilans' evaluative study will provide some answers, as it has the complementary benefits of both quantitative and qualitative methods.

**6. Funding**

This work was supported by regional agency of health of Hauts de France and Conseil Regional of Nord Pas de Calais

**7. Conflicts of interests**

The authors declare that they have no competing interest from the publication of this manuscript

**8. Author Contributions**

All authors were responsible for the development of the study design.  
GV and MW have conceived the algorithm. GV is responsible of the Vigilans system deployment.  
GV, CD, SD are responsible for coordinating the Vigilans system in Nord Pas de Calais Region.  
DD, ALD, SD and the clinical investigation center are responsible for inclusion of patients in the study, quality assurance and data collection.  
SD, CEN, SB, GV have been involved in writing up, revising and optimising the study protocol.  
GV, PT, FD, MW, PC, LJ, AM, TD are involved in the supervision of the work.  
All authors have read and corrected the draft versions and all authors contributed to and approved the final manuscript.

**Legends**

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Figure 1. Vigilans' territorial coverage in the Nord – Pas-de-Calais Region: inventory of the *Partner Centres*

Figure 2. Vigilans' algorithm for surveillance and Brief Contact Interventions provision

Figure 3. Data collection and evaluation timescales, as appraised through different levels of analysis. CS: completed suicide, SA: suicide attempt, KSS: Knowledge of Suicide Scale, MINI: Mini International Neuropsychiatric Interview, C-SSRS: Columbia Suicide Severity Rating Scale

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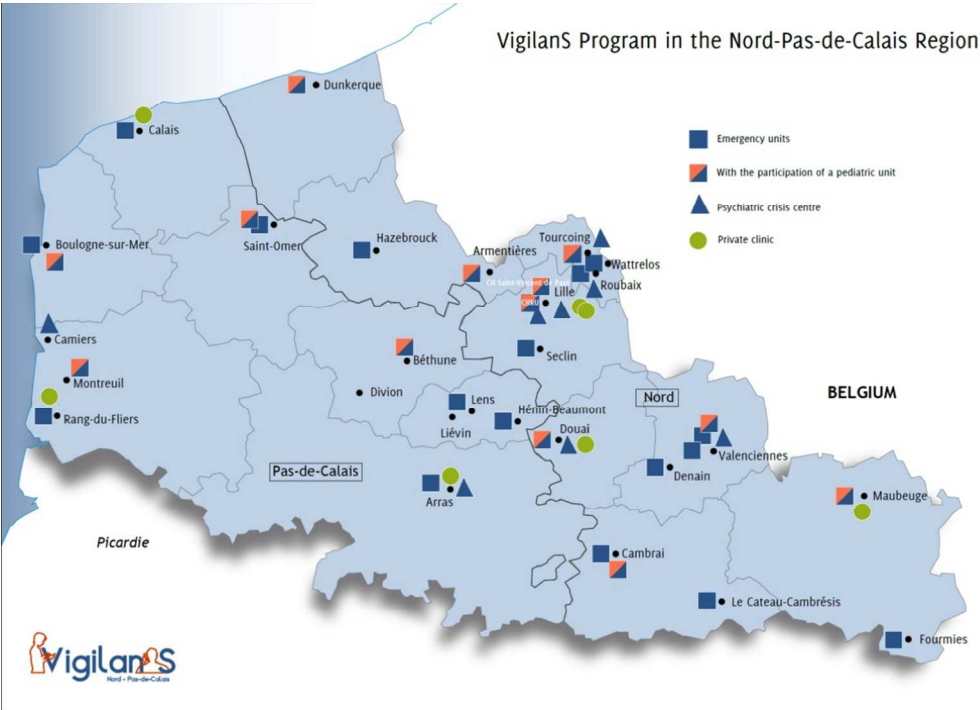
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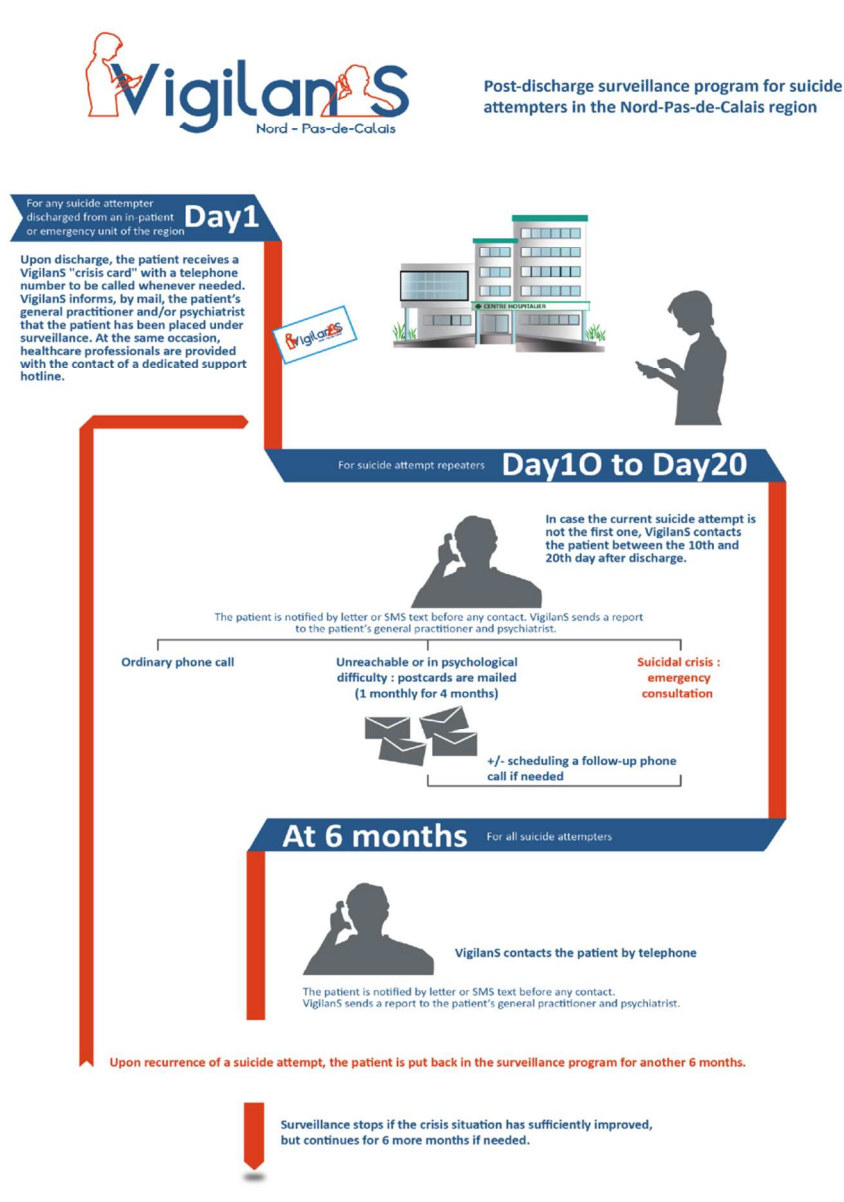
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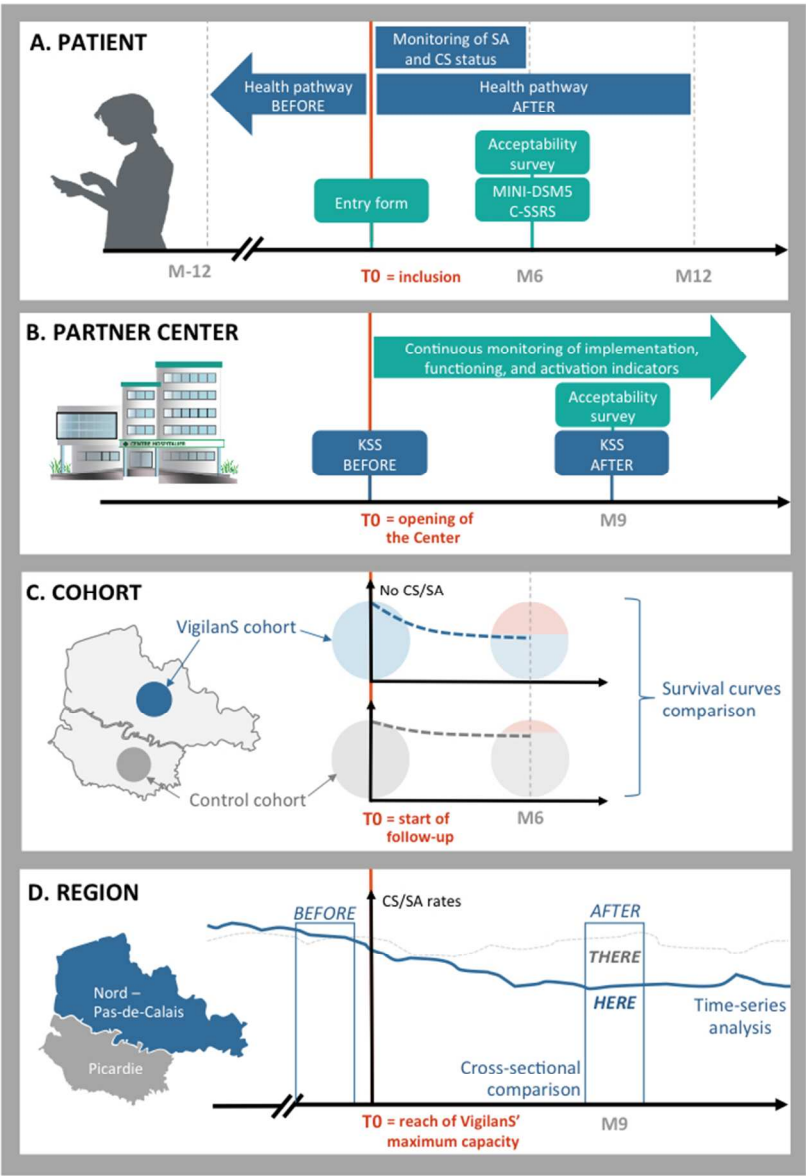
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Caption : To ensure satisfying territorial coverage, VigilanS recruited 28 Centers throughout the Nord-Pas-de-Calais Region



presentation of surveillance and BCI algorithm



summary of the timescales according to which we will collect data and carry out the analytical procedures