

# BMJ Open Combining brief contact interventions (BCI) into a decision-making algorithm to reduce suicide reattempt: the Vigilans study protocol

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**To cite:** Duhem S, Berrouiguet S, Debien C, *et al.* Combining brief contact interventions (BCI) into a decision-making algorithm to reduce suicide reattempt: the Vigilans study protocol. *BMJ Open* 2018;**8**:e022762. doi:10.1136/bmjopen-2018-022762

► Prepublication history for this paper is available online. To view these files, please visit the journal online (<http://dx.doi.org/10.1136/bmjopen-2018-022762>).

Received 19 March 2018  
Revised 7 June 2018  
Accepted 20 September 2018



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## ABSTRACT

**Introduction** The early postattempt period is considered to be one of the most at-risk time windows for suicide reattempt or completion. Among the postcrisis 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. Personalised 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 with 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 authorisation from the Ethical Committee of Lille Nord-Ouest under the caption 'Study aimed at evaluating routine care' and is registered in 'Clinical Trials'. The French Ministry of Health plans to extend the

## Strengths and limitations of this study

- Complementary methods and indicators are used to comprehensively and exhaustively assess the multi-stage effects of the Vigilans programme.
- 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 centres are challenging issues. However, we believe that this naturalistic setting will bring critical insight to future suicide-prevention guidelines.

experimentation to other regions and probe the relevance of this type of 'bottom-up' territorial prevention policy at the national level.

**Trial registration number** NCT03134885.

## INTRODUCTION

Presenting with a history of suicide attempt has been identified as one of the strongest and most robust risk factors for suicide completion. If the scope of prevention efforts must be narrowed for the sake of efficiency, focusing on suicide attempters in the immediate postdischarge period would be one of the most cost-effective strategies. Suicides occurring in the weeks after release from an inpatient ward were found to account for 5% of overall self-inflicted deaths,<sup>1</sup> owing to a suicide risk multiplied by 130 to 200 compared with the general population.<sup>2</sup>

Unfortunately, up-to-date evidence suggests that conventional healthcare provisions might not be sufficient to prevent reattempt and suicide completion in this highly

at-risk population.<sup>3</sup> Among the postcrisis systems that have proven their efficiency, two main approaches can be distinguished: intensive interventions, which consist of scheduling regular face-to-face therapeutic meetings structured around the acquisition of conflict resolution skills; and brief contact interventions (BCIs). Contrary to intensive interventions, BCIs aim at complementing typical treatment settings rather than replacing them. They serve two key objectives: (a) helping patients anticipate and cope with any new suicide crisis they might come to by providing reliable and efficient tools; and (b) proactively ensuring the preservation of a benevolent, non-intrusive link with healthcare systems. With respect to this last purpose, maintaining contact was found to be especially efficient if set on a regular, personalised and long-term basis.<sup>4</sup>

BCIs may take different forms:

- ▶ *Telephone calls* from the caregivers to the suicide attempters. The goal is to show concern for the patients and review with them the postdischarge protocol that was initially agreed on. This procedure was found to be especially efficient among those who attempted suicide more than once.<sup>5</sup>
- ▶ *Provision of a 'crisis card'* as described by Evans *et al.*<sup>6</sup> On discharge, patients are handed a *Green Card* stating a professional phone number that they can call 24/7 in case of distress. This system demonstrated more effectiveness for first attempters.
- ▶ *'Short letter' mailings*: Pioneered by Jérôme Motto and his postal contact strategy,<sup>7</sup> this case-management system consists of sending short letters to patients after their 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 personalised postcards based on the same time-frame as Motto, that is, at months 2, 3, 4, 5, 6, 8, 10 and 12 postdischarge.<sup>8</sup>
- ▶ *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.<sup>9</sup>

In 2015, Milner *et al* and Inagaki *et al* simultaneously published two meta-analyses assessing the effect of BCIs on suicide attempters.<sup>10 11</sup> Their converging conclusions suggested that patients benefited from the recontact procedures, showing significantly lower relapse and suicide rates when compared with treated-as-usual controls. While Milner *et al*, whose meta-analysis included three studies and 3549 patients, found that reattempts rate in the BCI patients were 0.66 times the reattempt rate of controls (95% CI: 0.54 to 0.80),<sup>10</sup> Inagaki *et al* calculated a similar BCI versus control IRR of 0.83 (95% CI: 0.71 to 0.97).<sup>11</sup>

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 postdischarge 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 led to either 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 10th and 21st days postdischarge. Similarly, proactive interventions or within-24-hour appointments were organised if the clinical team detected a high suicide risk. If the patients were unreachable or refused proactive care, the ALGOS team sent them postcards, in line with Carter's protocol.<sup>8</sup>

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 randomised controlled trial 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 with the rate from the treatment-as-usual group ( $p=0.024$ ).<sup>12</sup> 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 (three suicides in the ALGOS group vs eight 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 generalisation 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—renamed

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.

## OBJECTIVES

### 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:

- To implement an adaptive recontact system that smoothly and effectively combines surveillance and different types of BCIs that fit each patient's specific needs.
- To optimise the care management of patients discharged from the hospital after a suicide attempt by providing health stakeholders with standardised tools, effective skills and specialised literacy,
- 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.

### 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 generalisability 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 medicoeconomic sustainability.

A second line of secondary objectives was determined to specify the putative efficiency of the system, that is:

- ▶ Disclosing the consequences of its implementation for the patients' healthcare paths.
- ▶ Assessing its impact on the professionals' knowledge and representations about suicide.
- ▶ Characterising the profile of attempters who positively respond to the programme in terms of compliance and efficacy.

## VIGILANS SURVEILLANCE AND BCI SYSTEM

### 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, 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](#)).

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 formalised 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 hospitalisation (reported causes of the suicidal attempt, date of discharge, follow-up care, etc). On receipt of the medical note, Vigilans sends a letter to the GP with the notification that the patient has entered the programme.

### The algorithm

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

### Outgoing phone calls

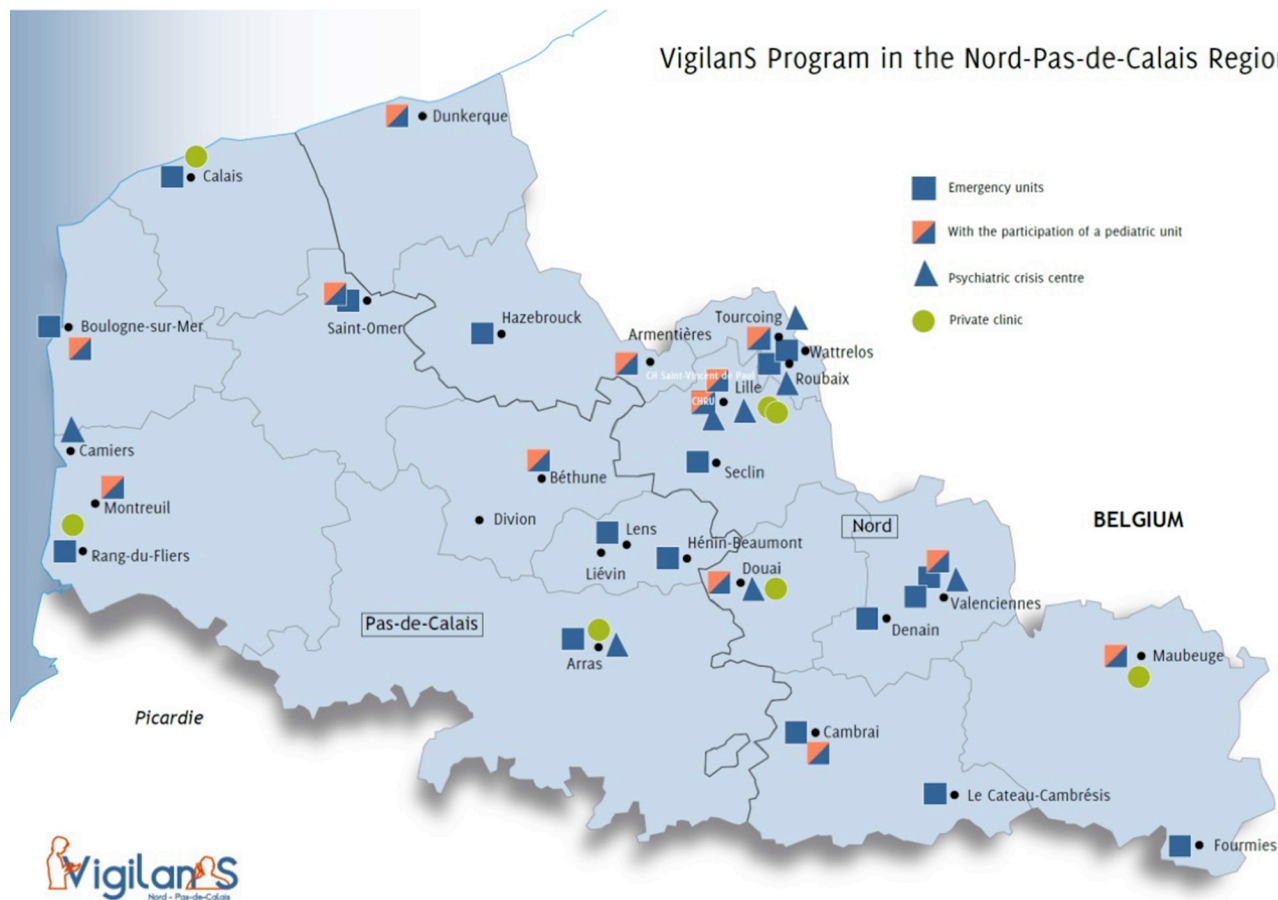
Each call will allow for controlling the suicide risk status, checking on compliance with follow-up care and involving new health professionals when necessary. After every call, a short report is sent to the patient's referral psychiatrist or GP. At each contact, the *call team* members may still decide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

### Ten-day calls

When the index suicide attempt is not the first one, patients are called 10–20 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. Operational setting 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 medicalised 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





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

support to close relatives or soliciting assistance from a proximal health professional. In addition to this crisis intervention, four 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 three call attempts scheduled at different days and different times, the programme sends him/her four postcards within 5 months.

#### Six-month calls

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 Diagnostic and Statistical

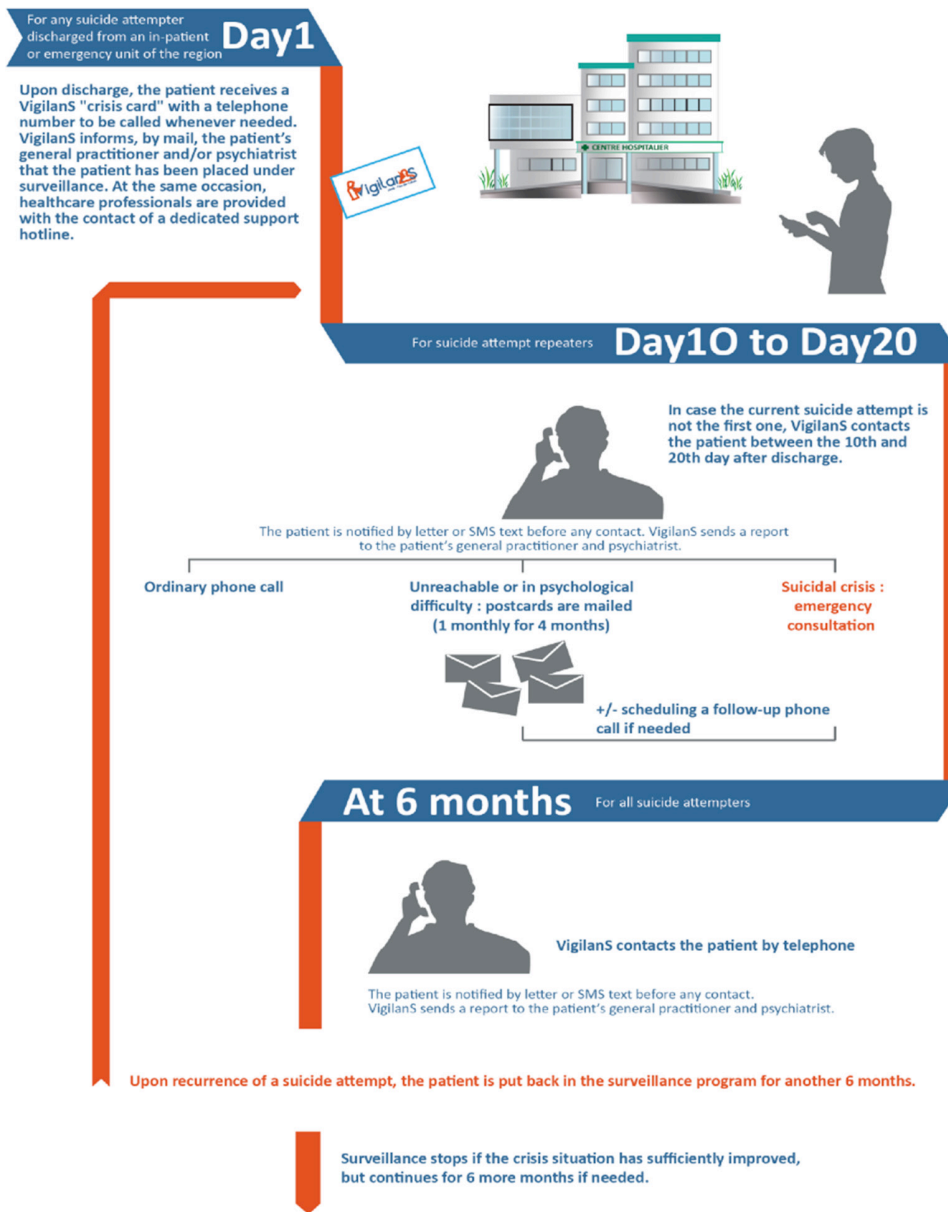
Manual of Mental Disorders (DSM-5))<sup>13</sup> and the Columbia Suicide Severity Rating Scale (C-SSRS).<sup>14</sup> In addition, patients are invited to respond to an online satisfaction questionnaire.

#### 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.

#### Postcards

As stated above, the postcard-sending system may be activated either systematically when the patient is unreachable or on 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 personalised. 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



**Figure 2** VigilansS' algorithm for surveillance and brief contact interventions provision. SMS, short message service.

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 re-attempt suicide or if the monitoring is reset.

#### 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 three 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 on by the professional partners.

#### Operational setting

The operational body of the system is split into two 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 centralises 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 three 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 VigilansS and medical emergency services. For this purpose, the Regional Emergency Medical Assistance Service of Lille agreed to host the *call team* in its dispatch centre, thus ensuring proximity and reactivity.

### 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 in figure 3.

#### Evaluation of VigilansS' efficacy with respect to its primary objective

##### Judgement criteria

VigilansS' 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 VigilansS' efficacy is composite and comprises suicide and suicide reattempt rates both in the VigilansS cohort and in the population of the Nord-Pas-de-Calais region.

##### Databases

The French Center for Epidemiology on Medical Causes of Death will provide the regional suicide mortality rates. Because French legislation does not authorise 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, a national register that records every admission, discharge and healthcare act in the French hospital system.

#### Procedure and analysis

To assess any possible effects of VigilansS on suicide and suicide attempt rates, we decided to break down the analytical procedure into two levels.

First, the follow-up design will allow for the performance of prospective analysis on the individual level. Patients who benefited from the BCIs and the surveillance system will be compared with 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.<sup>15</sup> 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 VigilansS versus belonging to the control cohort.

The second level of analysis will be populational. To evaluate the efficacy of VigilansS 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 (ie, 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, that is, 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 VigilansS' 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 (ie, before and after the implementation of the programme).

#### Evaluation of VigilansS' efficacy with respect to its secondary objectives

##### To evaluate the deployment of the programme

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

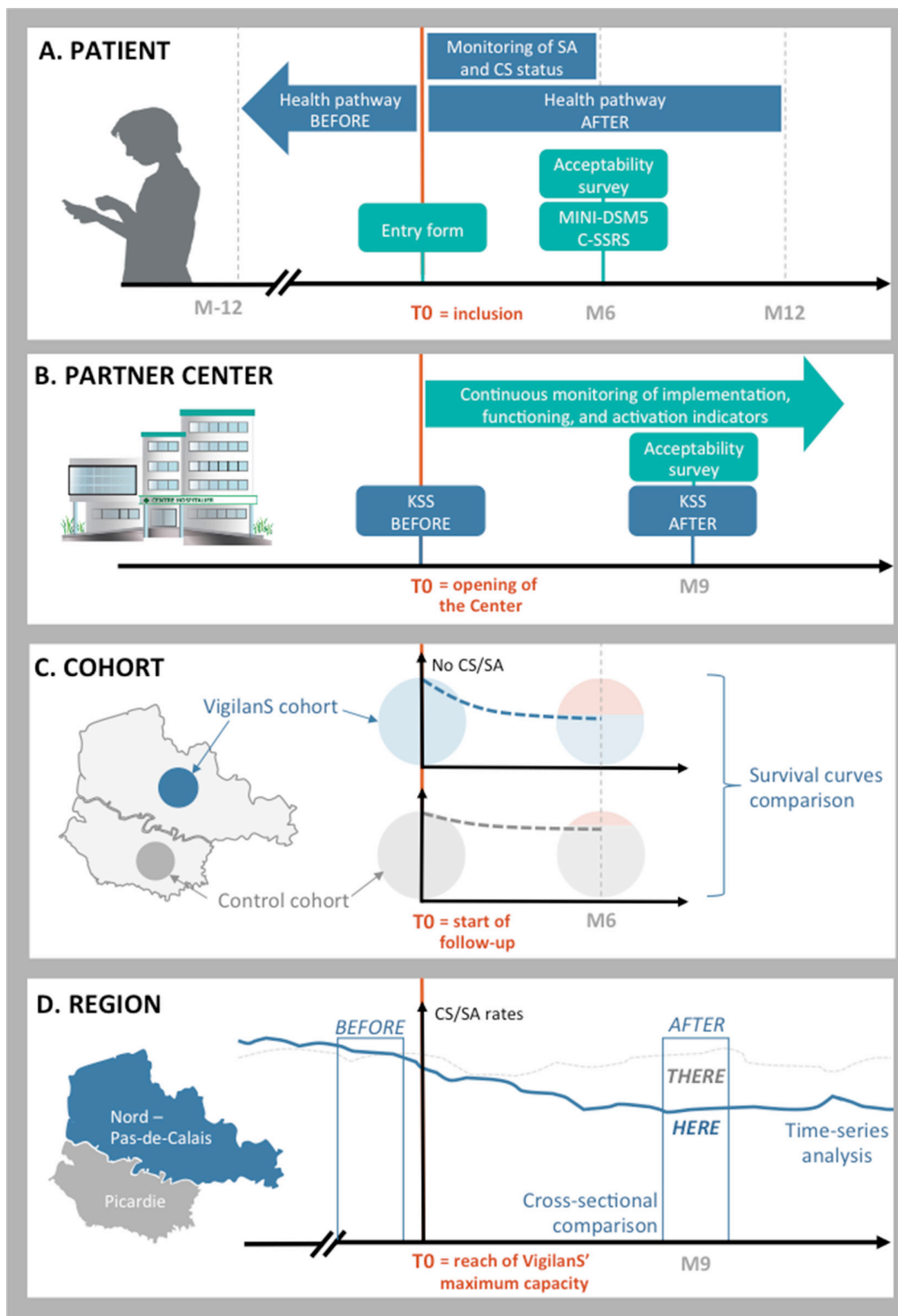
1. Its level of territorial implementation, as estimated by a 'penetrance rate', calculated as the number of patients included in the programme divided by the overall

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

	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 programme in terms of reduction of suicide and suicide reattempt rates in Vigilans cohort.	Suicide and suicide reattempt rates in the cohort.  <i>Sources: monitoring, CepiDC and PMSI.</i>	Prospective comparison with a control cohort via survival analyses.
		Assess the territorial effects of the programme 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, CepiDC and PMSI.</i>	Longitudinal interrupted time-series analysis cross-sectional here/there comparisons with Picardie's region data.
Proximal (secondary)	Implement an effective BCIs and surveillance system.	Measure the level of territorial implementation of the programme.	Penetration rate.	Description.
		Measure the functioning of the programme in terms of BCIs provision.	Number of Green Cards distributed. Number of outgoing calls. Number of postcards sent.	Description.
		Measure the acceptability of the programme.	Professionals' opinion about the possibility to integrate the programme in their practice. Patients' opinion about the efficiency and/or intrusiveness of the system.	Quantitative assessment: questionnaires. Qualitative assessment: semistructured interviews. Descriptive analysis.
	Optimise the care management of patients discharged from hospital after a suicide attempt.	Disclose the effects of the programme 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 versus 1 year after the entry in the programme.
		Assess the impact of the programme 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 centres.

BCI, brief contact intervention; CepiDC, French Center for Epidemiology on Medical Causes of Death; PMSI, Program for Medicalization of Information Systems.





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

number of admissions in the same period for the same indication.

- Its functioning, that is, 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 recur-

rent 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 generalisability 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.
- Qualitative appraisal: An independent experienced interviewer will conduct semistructured 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 optimise or correct the system.

4. *Its medicoeconomic viability.* Even if Vigilans is 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-step medicoeconomic assessment of the programme. First a microcosting 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 with 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 optimisation

According to one of our interventional expectations, Vigilans will optimise 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).

#### 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 categorised by each type of intervention (phone contact schedule, referral to GP or psychiatrist, dispatch of an emergency team, etc).

#### Characterisation of responder versus non-responder profiles

To characterise responder profiles, we will perform multivariate logistic regressions to predict the patients’ compliance and response to the programme 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 hospitalisations after the index suicide attempt.

#### Patient and public involvement

Vigilans is the release and generalisation of ALGOS as an open healthcare offer.

The ALGOS algorithm was evaluated by an independent team from the 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 is assessed by an ethic’s committee (where patient’s associations are presents).

The results will be disseminated to study participants per Vigilans website

#### ETHICS AND DISSEMINATION

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

- ▶ With regard to its interventional part (ie, 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 authorisation 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 under way. To test the generalisability 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 emphasised by Milner *et al*,<sup>10</sup> 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 psychopathological profile? Which adjustments are needed for patients suffering from personality disorders? 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.

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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, C-EN, 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.

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

**Competing interests** None declared.

**Patient consent** Not required.

**Ethics approval** Comité de protection des personnes Nord Ouest IV.

**Provenance and peer review** Not commissioned; externally peer reviewed.

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