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Patient-safety incidents during COVID-19 health crisis in France: an exploratory sequential multi-method study in primary care.

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Running title: Patient-safety incidents during COVID-19 pandemic

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Competing interests

The authors declare that they have no competing interests.

ABSTRACT

Background: The COVID-19 pandemic has resulted in rapid reorganization of health and social care services. Patients are already at significant risk of healthcare-associated harm and the wholesale disruption to service delivery during the pandemic stood to heighten those risks.

Objective: We explored the type and nature of patient safety incidents in French primary care settings during the COVID-19 first wave to make tentative recommendations for improvement.

Methods: A national patient safety incident reporting survey was distributed to General Practitioners (GPs) in France on April 28, 2020. Reports were coded using a classification system aligned to the WHO International Classification for Patient Safety (incident types, contributing factors, incident outcomes and severity of harm). Analysis involved data coding, processing, iterative generation of data summaries using descriptive statistical and thematic analysis. Clinicaltrials.gov: NCT04346121.

Results: Of 132 incidents, 58 (44%) related to delayed diagnosis, assessments and referrals. Cancellations of appointments, hospitalizations or procedures was reported in 22 (17%) of these incidents. Home confinement-related incidents accounted for 15 (10%) reports, and inappropriate stopping of medications for five (4%). Patients delayed attending or did not consult their general practitioner or other healthcare providers due to their fear of contracting COVID-19 infection at an in-person visit in 26 (10%) incidents, or fear of burdening their GPs in eight (3%) incidents.

Conclusion: Constraints arising from the first wave of the COVID-19 pandemic have contributed to patient safety incidents during non-COVID-19 care. Lessons from these incidents pinpoint where primary care services in France can focus resources to design safer systems for patients.

Keywords: patient safety incident, primary care, COVID-19, lockdown

Key message: A national primary care emergency response plan that supports primary care practitioners to organize communication with patients, screen vulnerable patients, and coordinate care in case of cancellations, could have mitigated most of the reported non-COVID-19-related incidents during the first wave.

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INTRODUCTION

Healthcare-associated harm is an established threat to public health and a source of avoidable harm to patients. More than 40 million patient safety incidents result in healthcare-associated harm worldwide annually [1]. Half of those patient harms are preventable [2], and almost all preventable incidents are systemic in nature and are inextricably linked to complex interactions between, for example, people, tasks, technology and organizational factors as well as external influences. The interrelationship between these system-wide factors give rise to safe or unsafe conditions and outcomes, depending on the context faced at the time.

The COVID-19 pandemic context has resulted in major disruptions to the delivery of healthcare services worldwide [3,4]. Lockdown announcements and successive governmental measures have caused wholesale disruptions in the routines of patients, providers, and overall care. Notably, equipment and/or beds have been relocated, and consequently surgeries and procedures have been cancelled or deferred for non-infected patients [5]. Combining these system-wide constraints risks an increase in patient safety incidents [6].

During the COVID-19 first wave, patient safety incidents have continued to occur in primary care settings. We aimed to identify the impact of the COVID-19 pandemic on the safety of care delivered to patients with non-COVID-19-related illnesses during the first wave to identify recommendations for system improvement efforts to manage subsequent waves or similar future crises.

METHODS

Study design and setting

We conducted an exploratory sequential multi-method study of patient safety incidents reported by general practitioners in France during the COVID-19 first wave.

Data collection

Patient safety incidents inclusion criteria

A patient safety incident is defined as “*an event or circumstance that could have resulted, or did result, in unnecessary harm to a patient*” [7]. The study population was patient safety incidents relating to the context of COVID-19 first wave in primary care, not those involving adverse clinical outcomes or complications or treatment of COVID-19 itself.

National patient safety incidents reporting platform

We built an online patient safety incident reporting platform, secured by Nantes University Hospital and based on the Royal College of General Practitioners Patient Safety Incident Reporting and Learning Guidance [8]. The home page gave the definition of a patient safety incident, and the objectives of the study (Supplementary Figures 1-3). A second page collected the characteristics of the reporter (age, department of practice, contact details), and their agreement to participate. A third page gathered data on the incident, including:

- i) patient characteristics: age, sex, social deprivation proxied by their health insurance status (*couverture santé solidaire*), patient history/factors that may have favoured occurrence of the incident (free-text field);
- ii) a free-text description of what happened, perceived reasons why the incident occurred, the outcomes and any mitigative actions taken (free-text field); and,

- iii) judgement about the likelihood of the incident occurring prior to the pandemic (Likert scale).

Selection of general practitioners

An email was sent on April 28, 2020 to the contact list of the *Collège National des Généralistes Enseignants (CNGE)*, which represent approximately 16,000 GPs, and inviting them to report patient safety incidents observed since March 17, 2020 (date of the French lockdown announcement). Only one reminder email was sent on May 28, 2020, to prevent over-solicitation of GPs at a particularly busy time of care delivery. GPs could report multiple incidents. This study covers incidents reported up to June 29, 2020.

Coder training

A team of six coders (four university GPs and two postgraduate general practice students) was trained to code patient safety incidents according to the methods developed by the Patient Safety (PISA) research group (Cardiff University), described below.

Data coding

Each free-text report was coded using the multi-axial PISA classification system, which is aligned to the World Health Organization International Classification for Patient Safety, and has been extensively used to characterize patient safety incidents data in primary care [9–13].

The PISA classification includes four coding frameworks, each designed to capture a different aspect of the patient safety incident:

- i) incident framework to characterize the events leading up to the outcome (*e.g.* delayed diagnosis of an emergency condition);

- ii) contributing factors framework to identify the circumstances, actions or influences reported to have played a part in the origin or development of an incident (*e.g.* (video-consultation limiting clinical assessment) [9]);
- iii) incident outcome framework to consider the impact on patients, staff and the organization (*e.g.* emergency surgery); and,
- iv) severity of harm framework to characterize the level of harm of the outcome (defined as no harm, low, moderate or severe harm, or death) classified in accordance with WHO definitions level [9].

Multiple codes for incident types, contributing factors and incident outcomes were applied if necessary (Figure 1). Codes were applied systematically and chronologically according to the nine rules of the Australian Patient Safety Foundation's Recursive Model of Incident Analysis. Primary incidents included those proximal (chronologically) to the patient outcome, whereas contributory incidents included those that contributed to the occurrence of another incident.

To clarify details for each submitted case, coders were able to contact reporters to gain additional information. Each report was randomly coded by two independent coders. In case of disagreement, reports were discussed in team meetings and with an external expert (ACS). Supplemental codes were added in the PISA classification to describe additional insights (type of incidents or contributing factors) when required.

Analysis

We conducted an exploratory sequential descriptive analysis of coded data. We generated cross-tabulations between incident types, contributory factors and outcomes. Priority areas

emerged from the most frequent semantic relationships between incident type and contributory factors. Recommendations to mitigate apparent risks associated with the priority areas were informed by the research team's awareness of the general practice context in France, iterative searches of the literature, and consultation with topic experts.

Ethical approval and confidentiality

The study protocol was prospectively recorded in clinicaltrials.gov (NCT0434612). Written informed consent was obtained from each participating general practitioner before reporting. This study was approved by the *CNGE* ethics committee, IRB00010804, advice n°27091852200409160. Minor changes were made in incident examples for illustrative purposes and to ensure confidentiality of patients and professionals.

RESULTS

Of 142 complete reports recorded on the online platform, 132 were included (Figure 1). There were 103 general practitioners reporting between one and four reports (mean: 1.3 ± 0.6).

Patients described in the reports were aged between 1 and 95 years old (mean: 56.1 ± 22.8), 74 (57%) were women, and 15 (12%) were considered socially deprived.

The 132 reports described 247 patient safety incidents in total (Table 1). Contributing factors are presented in Table 2. Overall, 285 outcomes (mean: 2.2 per report, Table 3) were identified, with 106 (80%) patient safety incidents having two or more explicit outcomes.

Related harms are presented in Table 4.

Delayed diagnoses and assessments (n=96)

Emergency conditions

Assessments were delayed for emergency conditions such as stroke (n=5, box 1), myocardial infarction (n=1), fracture (n=4, box 2), and complicated gastrointestinal infections (n=4).

Patients (and their relatives) delayed attending or did not consult their general practitioner and/or emergency departments for fear of contracting COVID-19 (n=9, example 1), and also expressed the fear of burdening their general practitioner, thinking that healthcare services were overwhelmed by COVID-19-related care (n=7, example 2).

Video-consultations complicated the assessment in two reports (general practitioner failed to diagnose an atrial fibrillation leading to a stroke; another could not examine a wrist that was fractured). Physicians overlooked common infections and focused on COVID-19 as their top differential diagnosis for two patients with serious infections and a fever.

Cancer

Ten other incidents concerned diagnoses of cancer (including seven initial diagnoses and two diagnoses of cancer progression). Healthcare services were unavailable, or consultations were delayed (n=8, example 3). Three patients with suspected breast cancer had their mammograms and biopsies postponed because the imaging practices were closed. Likewise, CT-scans for two gastrointestinal cancers had been postponed. Surgery was postponed for a patient with a suspicious skin lesion and another patient deteriorated due to postponement of prostate surgery.

Other conditions

Eighteen other incidents related to delayed diagnoses. From a patient perspective, the fear of contracting COVID-19 was also apparent (n=7), the fear to burden their general practitioner (n=3), and the misunderstanding of home confinement prohibited contact with medical services (n=3).

Video-consultation (n=2) created difficulties for diagnosing deep vein thrombosis or pyelonephritis. Closed health services (n=11, box 4) resulted in delayed secondary care consultations (gastroenterologist for anaemia investigation, orthopaedic surgeon for suspected hip dysplasia, closed service of maternal and child protection for pregnancy follow-up, nephrologist for severe hyperkalaemia following severe renal failure, n=4) or timely imaging (ultrasound for pyelonephritis, CT-scan for investigation of lymphadenopathy, n=5).

Delayed treatment (other than medication, n=22)

Clinical treatment (including physiotherapy), procedures, and surgeries have been delayed – either postponed or cancelled – pending the end of lockdown (examples 5 and 6). Services were not available for 18 patients (82%). Most of these incidents resulted in delays in the management of the patients (n=9, 41%). One patient died from a myocardial infarction that was managed too late because he had a fever and staff were waiting for COVID-19 test results before treating him. Another patient was known to suffer with epilepsy and was socially isolated and died at home from alcohol withdrawal during lockdown (his rehab hospitalization being postponed *sine die*).

Home confinement-related incidents (n=15)

Home confinement-related incidents involved typically patients with history of anxiety or depression (n=7), history of addiction (n=3), advanced age (n=4), or cognitive impairment (n=2) (example 6). For seven of these patients, home confinement led to incidents in connection with family issues through two main opposing mechanisms: i) isolation from family/relatives/carers (n=4, leading to disorientation or failure to cope, aggravation of anxiety disorder and/or depression, addiction relapse), or ii) strict home confinement leading to aggravation of intrafamilial violence (n=3). Twelve of those incidents were harmful; two (13%) of them led to deaths by suicide and failure to cope, three (20%) required hospitalizations, and six (40%) necessitated an introduction or adaptation of psychotropic medication to prevent further harm.

Medication-related incidents (n=21)

Medication-related incidents accounted for 21 (9%) incidents. Reasons for inappropriate stopping of medications (n=5) included a patient's own decision to stop immunosuppressants or chemotherapy for fear of contracting COVID-19 (n=2), stopping of non-steroidal anti-

inflammatory drugs (self-decision of patient or advice of a physician, n=2), an inability to pay for medication because of expired insurance-related rights (n=1), insufficient sharing of information between hospital and primary care professionals after hospital discharge (n=1), or due to a strict interpretation of home confinement where a patient refused to attend a pharmacist or general practitioner (n=4).

DISCUSSION

Main findings

Whilst efforts to cope with suspected COVID-19 patients were underway, we identified delays in diagnosis, assessments, referrals and treatments for patients with non-COVID-19 health problems, as well as complications arising from home confinement. Patients' fear of contracting COVID-19 in primary care facilities, and their fear of burdening their general practitioners, have contributed to their poor care and related health outcomes.

Strengths and limitations

The COVID-19 pandemic sparked an international collaboration between academic general practitioners in France and international patient safety experts. We have used a structured and validated approach, aligned to the WHO International Classification for Patient Safety, to investigate the impact of the COVID-19 pandemic on patients seeking primary care services for non-COVID-19 illnesses.

There is no established patient safety incident reporting culture in France, therefore we were extremely heartened that 103 general practitioners took the time to describe between one and four patient safety incidents. That said, participation of general practitioner was still lower than expected and this may reflect a phenomenon of excessive solicitation via surveys in the context of COVID-19 pandemic. However, these reports have identified learning that would have otherwise been lost in history with no way of honouring those patients that have suffered the consequences of healthcare-associated harm.

Incident reports are notoriously variable in data quality, and to mitigate this we sought to clarify report narratives with general practitioners where there were any uncertainties in the

case. Overall, whilst these study results should be considered as exploratory, we present important signals that should be interpreted as opportunities for general practitioners and their teams to improve their own processes to mitigate avoidable harm to patients. More detailed investigation of incidents at a local- and national-level, supported by a systems theory-based framework such as Accimaps [14,15], should explore organizational, regulatory and governmental level contributory factors.

Interpretation of results in relation to existing literature

Gandhi and Singh cautioned early in the COVID-19 pandemic that delayed “diagnosis of acute non-COVID-19 diagnoses” would be mediated by “patients not coming in for evaluation due to infection risk” [6]. Previous reports from the secondary care setting have illustrated the impact of this patient fear in the increased delay of hospital care for myocardial infarction [16,17], or in the paediatric population with emergency conditions [18].

Delayed diagnosis when appointments for imaging or elective procedures were cancelled was particularly harmful for patients with acute conditions and cancer signs or symptoms. We also observed delayed diagnoses as a result of telemedicine use.

The identification of incidents directly related to home confinement question its strict application among the most vulnerable [19,20].

Implications for practice and policy

In light of the study results, we propose the following recommendations for system improvement efforts.

Addressing fear of contracting COVID-19 in general practice offices and fear of burdening general practitioners through close communication with patients

Our study results highlight that some patients may have erroneous ideas about infection control management in their general practice offices or the workload of their general practitioners. Improved direct communication to counter and overcome these misconceptions with the population could mitigate this confusion. Related, practices should review and update preferred contacts for patients.

Addressing prevention of home confinement consequences through proactive and repeated contacts with vulnerable patients

Three weeks after the beginning of lockdown, French general practitioners were advised to proactively get in touch with their “most fragile patients with chronic conditions” [21]. Other guidelines recommended, similarly, to prioritize and proactively contact vulnerable patients (at risk of infection, with uncontrolled chronic disease, or experiencing social needs) to invite them to periodically check-in [22]. Our study results suggest that those criteria should be extended to patients with addiction. External assistance to assist general practitioners may be necessary to efficiently perform this additional task [23].

Addressing the maintenance and follow-up of necessary care through coordination and communication with secondary care

Our study identified the need for transparent communication processes between primary and secondary care for referrals and imagine requests. Notably, systems are needed for escalating concerns about patients as well as the provision GPs to access secondary care opinions via teleconferencing.

CONCLUSION

Major concerns have been raised about the quality and safety of non-COVID-19 care during the COVID-19 pandemic. The incidents we identified highlight a lack of preparedness to the unprecedented magnitude of the pandemic. We identified powerful signals from the first wave of the pandemic which pinpoint where primary care services in France can focus resources to design safer systems for patients. In doing so, there is an opportunity to mitigate further similar patient safety incidents during subsequent waves or similar future crises.

REFERENCES

- [1] Jha AK, Larizgoitia I, Audera-Lopez C, et al. The global burden of unsafe medical care: analytic modelling of observational studies. *BMJ Qual Saf.* 2013;22:809–815.
- [2] Panagioti M, Khan K, Keers RN, et al. Prevalence, severity, and nature of preventable patient harm across medical care settings: systematic review and meta-analysis. *BMJ.* 2019;366.
- [3] Fisher D, Teo YY, Nabarro D. Assessing national performance in response to COVID-19. *The Lancet.* 2020;396:653–655.
- [4] Cash R, Patel V. Has COVID-19 subverted global health? *The Lancet.* 2020;395:1687–1688.
- [5] Myles PS, Maswime S. Mitigating the risks of surgery during the COVID-19 pandemic. *The Lancet.* 2020;396:2–3.
- [6] Gandhi TK, Singh H. Reducing the Risk of Diagnostic Error in the COVID-19 Era. *J Hosp Med.* 2020;15:363–366.
- [7] Sherman H, Castro G, Fletcher M, et al. Towards an International Classification for Patient Safety: the conceptual framework. *Int J Qual Health Care.* 2009;21:2–8.
- [8] Carson-Stevens A, Donaldson LJ. Reporting and learning from patient safety incidents in general practice: a practical guide [Internet]. Royal College of General Practitioners; 2017 [cited 2021 Apr 29]. Available from: <https://www.rcgp.org.uk/-/media/Files/CIRC/Patient-Safety/Reporting-and-learning-from-patient-safety-incidents.ashx?la=en>.
- [9] Carson-Stevens A, Hibbert P, Williams H, et al. Characterising the nature of primary care patient safety incident reports in the England and Wales National Reporting and Learning System: a mixed-methods agenda-setting study for general practice [Internet]. Southampton (UK): NIHR Journals Library; 2016 [cited 2021 Apr 29]. Available from: <http://www.ncbi.nlm.nih.gov/books/NBK385186/>.

- [10] Williams H, Edwards A, Hibbert P, et al. Harms from discharge to primary care: mixed methods analysis of incident reports. *Br J Gen Pract.* 2015;65:e829-837.
- [11] Rees P, Edwards A, Powell C, et al. Patient Safety Incidents Involving Sick Children in Primary Care in England and Wales: A Mixed Methods Analysis. Shekelle P, editor. *PLoS Med.* 2017;14:e1002217.
- [12] Evans HP, Anastasiou A, Edwards A, et al. Automated classification of primary care patient safety incident report content and severity using supervised machine learning (ML) approaches. *Health Informatics J.* 2020;26:3123–3139.
- [13] Cooper J, Edwards A, Williams H, et al. Nature of Blame in Patient Safety Incident Reports: Mixed Methods Analysis of a National Database. *Ann Fam Med.* 2017;15:455–461.
- [14] Rasmussen J. Risk management in a dynamic society: a modelling problem. *Safety Science.* 1997;27:183–213.
- [15] Branford K. Seeing the Big Picture of Mishaps: Applying the AcciMap Approach to Analyze System Accidents. *Aviation Psychology and Applied Human Factors.* 2011;1:31–37.
- [16] Hammad TA, Parikh M, Tashtish N, et al. Impact of COVID-19 pandemic on ST-elevation myocardial infarction in a non-COVID-19 epicenter. *Catheter Cardiovasc Interv.* 2020;
- [17] Masroor S. Collateral damage of COVID-19 pandemic: Delayed medical care. *Journal of Cardiac Surgery.* 2020;35:1345–1347.
- [18] Ciacchini B, Tonioli F, Marciano C, et al. Reluctance to seek pediatric care during the COVID-19 pandemic and the risks of delayed diagnosis. *Ital J Pediatr.* 2020;46:87.
- [19] Gibson J. Domestic violence during COVID-19: the GP role. *Br J Gen Pract.* 2020;70:340.
- [20] Roesch E, Amin A, Gupta J, et al. Violence against women during covid-19 pandemic restrictions. *BMJ.* 2020;369:m1712.

- [21] Direction générale de la Santé. Organisation des soins hors COVID-19 [Internet]. 2020 [cited 2021 Apr 29]. Available from: <https://dgs-urgent.sante.gouv.fr/dgsurgent/inter/detailsMessageBuilder.do?id=30752&cmd=visualiserMessage>.
- [22] Krist AH, DeVoe JE, Cheng A, et al. Redesigning Primary Care to Address the COVID-19 Pandemic in the Midst of the Pandemic. *Ann Fam Med*. 2020;18:349–354.
- [23] University Hospital, Tours. Does a Systematic Phone-call by a Medical Student/General Practitioner Team in Patients Suffering From a Chronic Condition During the COVID-19 Containment Period Impact One-month Hospitalization's Rate in France? A Cluster Randomized Trial [Internet]. clinicaltrials.gov; 2020 [cited 2021 Apr 29]. Report No.: NCT04359875. Available from: <https://clinicaltrials.gov/ct2/show/NCT04359875>.

FIGURES

Figure 1: Examples of codes from the classification system using the Recursive Model of Incident Analysis

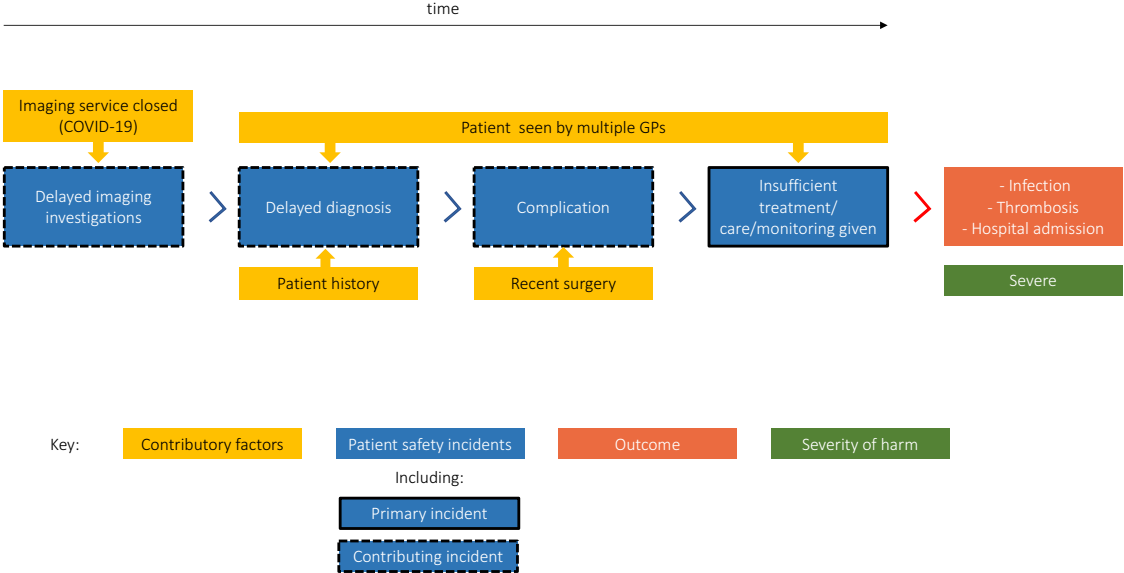
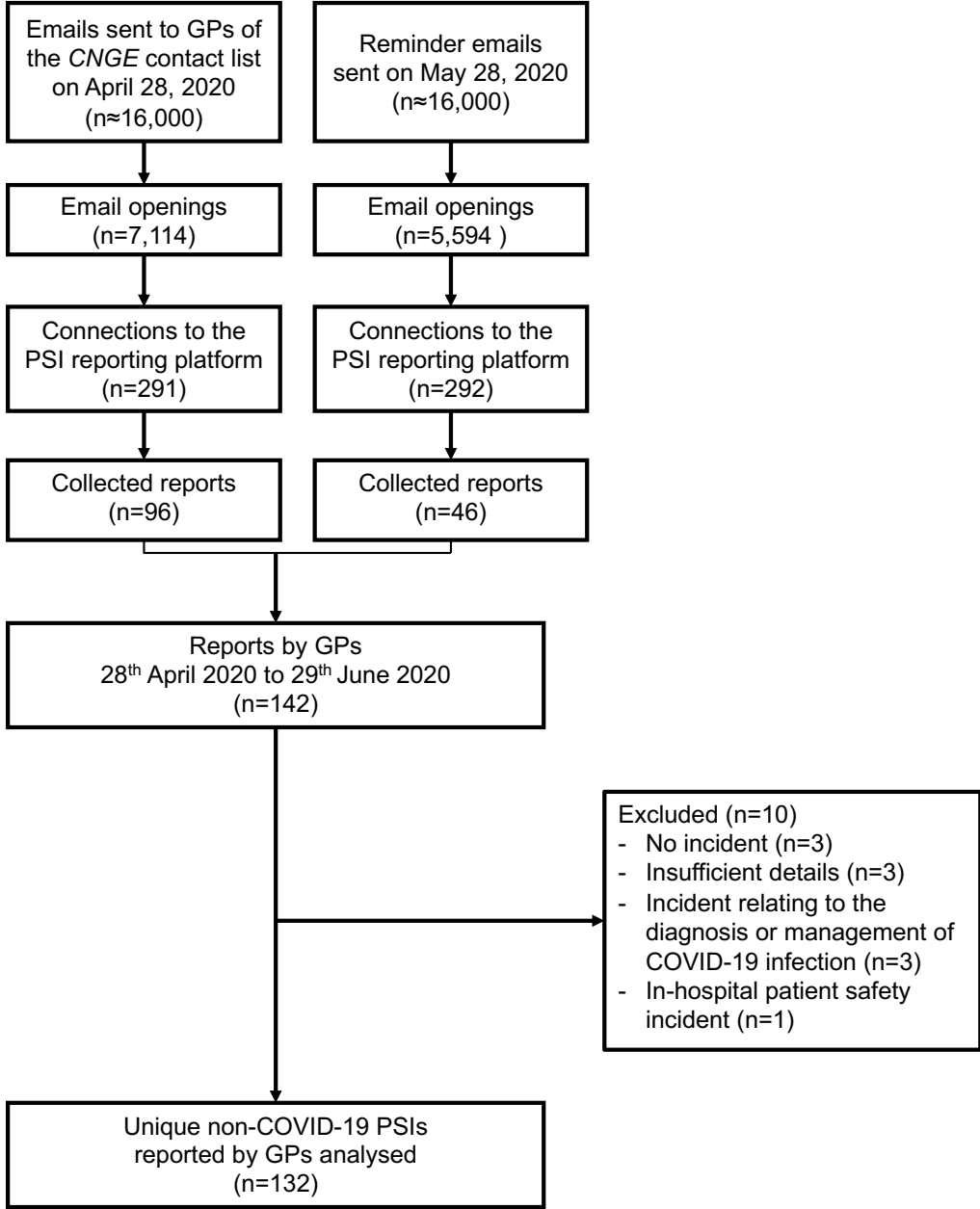


Figure 2: Flow diagram of collected, included and excluded patient safety incident reports



GPs: General Practitioners
 CNGE: Collège National des Généralistes Enseignants
 PSI : Patient Safety Incident

TABLES

Table 1- Types of 247 patient safety incidents (132 primary incidents and 115 contributing incidents) described in the 132 reports

Incidents types ^a	Primary incidents ^b (n=132)	All incidents (n=247)
Diagnosis, assessment & referral	58 (43.9)	96 (38.9)
Diagnosis	45 (34.1)	55 (22.3)
Delayed diagnosis of an emergency condition	18 (13.6)	18 (7.3)
Delay of initial diagnosis of cancer	6 (4.5)	7 (2.8)
Delayed diagnosis (unspecific)	17 (12.9)	18 (7.3)
Other	0 (0.0)	12 (4.9)
Process of assessment	8 (6.1)	27 (10.9)
Delayed assessment	4 (3.0)	9 (3.6)
Errors in the process of identifying patients with acute or serious conditions	3 (2.3)	8 (3.2)
Other	1 (0.8)	10 (4.0)
Incorrect referral	4 (3.0)	10 (4.0)
Other	1 (0.8)	4 (1.6)
Treatment and procedures	43 (32.6)	50 (20.2)
Delayed treatment	22 (16.7)	22 (8.9)
Home confinement complications	13 (9.8)	15 (6.1)
No treatment/care given	6 (4.6)	7 (2.8)
Other	2 (1.6)	6 (2.4)
Investigations	8 (6.1)	28 (11.3)
Diagnostic imaging investigations	3 (2.3)	16 (6.5)
Delayed imaging investigations	1 (0.8)	11 (4.5)
Other	2 (1.6)	5 (2.0)
Laboratory investigations	3 (2.3)	7 (2.8)
Other investigations	2 (1.6)	5 (2.0)
Administrative	3 (2.3)	32 (13.0)
Errors in managing healthcare appointments	1 (0.8)	18 (7.3)
Secondary care appointments	1 (0.8)	15 (6.1)
Other	0 (0.0)	3 (1.2)
Inability to reach out physician	2 (1.6)	7 (2.8)
Incorrect or inefficient transfer of patient information across healthcare systems	0 (0.0)	5 (2.0)
Other	0 (0.0)	2 (0.8)
Medication	16 (12.1)	21 (8.5)
Medication stopped	5 (3.8)	5 (2.0)
Other	11 (8.3)	16 (6.5)
Communication errors	1 (0.8)	15 (6.1)
Between professionals and patients	1 (0.8)	9 (3.6)
Between professionals	0 (0.0)	5 (2.0)
Other	0 (0.0)	1 (0.4)
Other	3 (2.3)	5 (2.0)

^aValues presented as n (%)”

Primary incidents: incidents chronologically closest to the outcome of the incident for the patient.

Contributing incidents: incidents that contributed to the occurrence of another incident.

Table 2. Contributing factors underpinning the 132 primary patient safety incidents

Contributing factors types ^a	Total (n=263)
Patient factors	163 (62.0)
Pathophysiological factors	91 (34.6)
Previous health/medication history	24 (9.1)
Patient confined at home	18 (6.8)
Physical or mental disability	14 (5.3)
Multimorbidity	8 (3.0)
Child	3 (1.1)
Other	24 (9.1)
Patient and/or relatives' knowledge	36 (13.7)
Fear of contracting Covid-19 in healthcare facilities	26 (9.9)
Fear of burdening General Practitioner	8 (3.0)
Other	5 (1.9)
Behaviour	13 (4.9)
Age	3 (1.1)
Other	20 (7.6)
Organizational factors	86 (32.7)
Reported or cancelled care due to unavailable or closed services	52 (19.8)
Secondary care consultations	19 (7.2)
Imaging	14 (5.3)
Surgery or procedures cancelled/reported	13 (4.9)
Physiotherapist	8 (3.0)
Laboratory	2 (0.8)
Other	5 (1.9)
Continuity of care	14 (5.3)
Between Secondary and Primary Care	9 (3.4)
Others	5 (1.9)
Working conditions	6 (2.3)
Video-consultations	5 (1.9)
Others	8 (3.0)
Healthcare professional factors	10 (3.8)
Equipment factors	1 (0.4)

^aValues presented as n (%)

Table 3 – Types of outcomes of the 132 primary patient safety incidents

Outcomes types^a	Total (n=285)^b
Unclear outcome	3 (1.1)
No outcome	14 (4.9)
Healthcare professional identified incident and mitigated outcome	5 (1.7)
Patient, relative or carer identified incident and mitigated outcome	2 (0.7)
Other	7 (2.4)
Patient clinical outcomes	122 (42.8)
Pathophysiological or disease-related outcomes	79 (27.7)
Discomfort/pain	11 (3.9)
General deterioration/progression of condition	25 (8.8)
Other	41 (14.4)
Psychological distress	25 (8.8)
Anxiety	6 (2.1)
Psychological difficulty requiring treatment	6 (2.1)
Other	12 (4.2)
Death	8 (2.8)
Other	10 (3.5)
Patient non-clinical outcomes	124 (43.5)
Delays in management (assessment or treatment)	69 (24.2)
Hospital admission	36 (12.6)
Emergency department or casualty	8 (2.8)
Emergency surgery	8 (2.8)
Hospital admission (unspecific)	20 (7.0)
Additional monitoring required	6 (2.1)
Other	13 (4.6)
Organizational outcomes	13 (4.6)
Primary care staff outcomes	9 (3.2)

^aValues presented as n (%)”

^bSome incidents have generated several outcomes

Table 4 – Harm severity of the 132 primary patient safety incidents

Harm severity^a	Primary incidents (n=132)
Unclear harm	33 (25.0)
Unharmful incidents	11 (8.3)
No harm	5 (3.8)
No harm due to mitigating action	6 (4.5)
Harmful incidents	88 (66.7)
Low harm	19 (14.4)
Moderate harm	29 (22.0)
Severe harm	30 (22.7)
Deaths	10 (7.6)

^aValues presented as n (%)

Box 1 – Free-Text Examples of Key Incidents

Example 1

The patient fell on her wrist: there was a clinical fracture, and the patient was completely unable to use her arm. Rural area. Usually we have access to imaging practice 10 km from the medical home and if [fracture] not displaced, we plaster (resin) or [use] thermoformed orthosis in the medical home. Because of the confinement, the local imaging practice was closed and orientated us to another practice 30 km away. So, I sent the patient to the emergency service for imaging and treatment since the delays would be too to carry out the usual outpatient care. I called the emergency service to let them know. But I learned the same evening when I called the patient back that she did not go there because she was afraid of encountering COVID. I called her daughter and her granddaughter to ensure she'd be taken care of the next day. Delayed treatment with no consequences since there was no vascular, neuro or cutaneous harm from the fracture in the end.

Example 2

Visual concern on the evening of mid-April; starting with a feeling of cold and pain in the right frontoparietal area [lasting] 3-4 days, then persistent visual disturbance on the left visual field; some dizziness [...]; the patient thought he had hypoglycaemia (with a feeling of dizziness) and did not consult [me] until end of April for his "renewal of treatment". Patient "didn't want to burden" me (thinking I was overwhelmed in the context of COVID-19). Cerebral scan [... then] MRI: subacute stroke, [...] therefore probably irreversible sequelae (homonymous hemianopia). Contributing factor: patient history, social context.

Example 3

Patient with history of carcinoma, CLL, type 2 diabetes. In December 2019, I requested an ultrasound scan and a surgical opinion for new lesions and lymphadenopathies following surgery. Ultrasound in January 2020 confirmed the suspect nature of the lymphadenopathies. Appointments with the surgeon (end of January) and the oncologist (early February 2020) were scheduled. CT-scan, biopsy and hospital appointments also scheduled. Letters received. Then nothing... Lockdown began. Mid-April 2020, I saw the patient again for transient diplopia. I tried to get the CT-scan report, but the practice was unreachable and I learned that there has been a PET-scan of which I didn't have the results since the service was also unreachable. I managed to reach oncology [department], which did not have the results either, and realized that the patient had not been summoned for [her] hospitalization. She also had great difficulty in recovering the results, which showed a melanoma with numerous distant metastases. HUGE communication problems related in my opinion to two causes: general practitioners are not systematically recipients of complementary exams and the confinement has complicated the follow-up of patients.

Example 4

Cerebral MRI scan prescribed by an ophthalmologist for decreased visual acuity revealing compressive meningioma. Following appointment with the ophthalmologist was scheduled but this was cancelled by his secretary without proposal of another appointment or recall. Lack of vigilance from specialist who prescribed the MRI and/or wrong instructions given to his secretary [resulting in an] outright cancellation of an appointment. The patient came to my consultation not knowing what to do. I quickly referred her to a neurosurgeon who was considering surgery but with a much longer delay, given the context. Surgery was postponed to the end of June due to the health context (according to the neurosurgeon's report). She told me that she had completely lost vision in her right eye and more than half of her left visual field. She [now] needs permanent assistance of a third person.

Example 5

Patient who had an elbow dislocation before confinement. He kept his splint on for 4 weeks which was too long. As a result, he had his elbow locked at 90 degrees. He called several physiotherapists who could not see him via a consultation because physiotherapy practices were closed. He was left to himself without a follow-up consultation and no access to specialist advice. He did not call the general practitioner for advice because he did not want to disturb the general practitioner during the pandemic. When he consulted three weeks later, he was still fixed at 90 degrees. Despite the confinement and [thanks to] my call for a physiotherapist, he was able to start rehabilitation which will take a very long time. This poses considerable risks for a young patient and longer sick leave from work is expected now.

Example 6

A patient with anxiety, depression, alcohol dependence, and history of physical violence was socially isolated from family during confinement. As a result, the patient developed increased anxiety, increased alcohol consumption, and became irritable and admitted verbal abuse of the primary caregiver at home. [The patient was not *a priori* identified by the general practice as being vulnerable and at risk of health deterioration due to the confinement.] Anxiolytic treatment, psychotherapy and follow-up by close video-consultations [were arranged after delays].