

Title : Point-of-Care Ultrasound use by
general practitioners in France.

NCT04583670

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STATISTICAL ANALYSIS PLAN

1. Abbreviations and Definitions

GP	General practitioner
POCUS	Point-of-Care Ultrasound
95% CI	95% Confidence interval

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3. Introduction

3.1. Study Outcomes

The aim of this study is to describe the use of POCUS and its role in the diagnostic and therapeutic process in general medicine.

- Description of the use of POCUS through indication, organs scanned, findings, frequency , time consumption.
- Analysis of the role of POCUS in the diagnostic process: change of diagnostic hypotheses and change of certainty in the main diagnostic hypothesis.
- Analysis of the role of POCUS in the therapeutic process: change in the care pathway/referral plan and the therapeutic initial plan.

This is an observational study without any intervention.

3.2. Study design

This study is an observational, prospective and multicenter study. General Practitioners (GP) who were recruited had to complete a questionnaire with a "pre-post" design with questions about consultation before POCUS (Q1-Q14), a timelog for ultrasound performance and additional questions about the consultation after POCUS (Q15-Q29).

3.2.1. Questionnaire BEFORE POCUS

Question Number	Question	Possible Answers	Answer format
Q1	GP ID Number	A à Z or AA à AM	1 or 2 letters
Q2	Patient ID number	A1 to Z26 and AA1 to AM26	1 or 2 letters follow by 2 digits
Q3	Date	2022-11-17 to 2024-06-06	AAAA-MM-JJ
Q4	Patient gender	Man, Woman or Other	Single answer question
Q5	Patient Age	0 to 120	Number with 1 to 3 digits
Q6	Setting of POCUS	<ul style="list-style-type: none">- At patient's home- At medical office- Other, to specify	Single answer question
Q7	What is the main reason to use POCUS in this patient ?	<ul style="list-style-type: none">- Answer to a specific clinical question (answer yes/no/maybe) and document the answer in patient's medical record- Therapeutic Education- Follow or Control an echographic	Multiples answers question

		signal - Screen an asymptomatic patient - Training without clinical benefit - Analyse and describe in detail an anatomical structure with multiples organs and edit a complete report	
Q8	Anatomical areas planned to be scanned	- Abdominal/Urologic - Gynecologic-Obstetrical - Musculoskeletal - Vascular - Thoracic - Other/Superficial	Multiples answers question
Q9	Organs planned to be scanned	- Gallbladder, Kidneys, Liver, Spleen, Pancreas, Morisson's pouch, Bladder, Prostate, Testes, Douglas pouch, Other abdominal structures - Uterus, Ovaries, Gestational sac, Embryo, Douglas pouch, Other gynecological/obstetric structures - Joint, Joint infiltration, Muscle, Tendon, Bone, Other musculoskeletal structures - Aorta, Deep veins of the lower limbs, Carotid arteries, other vascular structures - Lungs, Pleura, Heart, Other thoracic structures - Thyroid, Tissues, Lymph nodes, Breasts, Other superficial structures	Multiples answers question
Q10	What is the main tentative diagnosis for this patient ?	ICPC2 code	1 letter followed by 2 digits
Q11	Are there any other possible tentative diagnoses in this case ?	Yes / No	Single answer question
Q12	Second, Third and Fourth tentatives diagnoses	ICPC2 code	1 letter followed by 2 digits
Q13	GP's overall / referral plan for the patient before POCUS use	- Acute admission to hospital - Subacute referral (2-3 days) to hospital - Elective referral to hospital - Subacute referral (2-3 days) to specialist - Elective referral to specialist - Referral to radiology, and which imaging prescribed (radiography, échography, Scanner, IRM) - Outpatient follow-up - No plan for follow-up - Other referral (physiotherapist...), to	Multiples answers question

		specify	
Q14	Which treatment will you initiate at this stage ?	<ul style="list-style-type: none"> - Medication - I will refer for treatment - I will initiate other treatment - No treatment - Other 	Multiples answers question

3.2.2. Questionnaire AFTER POCUS

Question number	Question	Possible Answers	Answer format
Q15	How much time did you use on the POCUS examination ?	Minutes	Number with 1 to 3 digits
Q16	Anatomical areas scanned	<ul style="list-style-type: none"> - Abdominal/Urologic - Gynecologic-Obstetrical - Musculoskeletal - Vascular - Thoracic - Other/Superficial 	Multiples answers question
Q17	Organs scanned	<ul style="list-style-type: none"> - Gallbladder, Kidneys, Liver, Spleen, Pancreas, Morisson's pouch, Bladder, Prostate, Testes, Douglas pouch, Other abdominal structures - Uterus, Ovaries, Gestational sac, Embryo, Douglas pouch, Other gynecological/obstetric structures - Joint, Joint infiltration, Muscle, Tendon, Bone, Other musculoskeletal structures - Aorta, Deep veins of the lower limbs, Carotid arteries, other vascular structures - Lungs, Pleura, Heart, Other thoracic structures - Thyroid, Tissues, Lymph nodes, Breasts, Other superficial structures 	<p>Multiples answers question</p> <p>Some free text to specify which organs were explored by GP when they check "Other" boxes</p>
Q18	Were you able to produce ultrasound images of the relevant structures of [each selected organ Q17]?	Yes / No	Single answer question
Q19	What did you find ?	<ul style="list-style-type: none"> - Certain positive findings - Uncertain positive findings - Certain negative findings - Uncertain negative findings - Incidental findings 	<p>Multiples answers question</p> <p>Free text to specify which incidental finding GP found</p>

Q20	Have your diagnostic hypotheses changed?	Yes / No	Single answer question
Q21	What is the diagnostic hypothesis for the patient now ?	ICPC2 Code	1 letter followed by 2 digits
Q22	Are there any other possible diagnostic hypotheses for this patient ?	Yes / No	Single answer question
Q23	Second, third and fourth diagnostic hypotheses after POCUS performed	ICPC2 Code	1 letter followed by 2 digits
Q24	Were you able to eliminate certain hypotheses ?	Yes / No	Single answer question
Q25	How is your confidence in your main diagnostic hypothesis, after you have used POCUS ?	<ul style="list-style-type: none"> - Highly increased confidence - More confidence - Unchanged confidence - Less confidence - Highly reduced confidence 	Single answer question
Q26	Has your overall / referral plan changed ?	Yes / No	Single answer question
Q27	What is your overall / referral plan for this patient now ?	<ul style="list-style-type: none"> - Acute admission to hospital - Subacute referral (2-3 days) to hospital - Elective referral to hospital - Subacute referral (2-3 days) to specialist - Elective referral to specialist - Referral to radiology, and which imaging prescribed (radiography, échography, Scanner, IRM) - Outpatient follow-up - No plan for follow-up - Other referral (physiotherapist...), to specify 	Multiples answers question
Q28	Has your initiated treatment for this patient changed ?	Yes / No	Single answer question
Q29	Which treatment will you initiate at this stage ?	<ul style="list-style-type: none"> - Medication - I will refer for treatment - I will initiate other treatment - None - Other 	Multiples answers question

GP's characteristics

3.2.3. Questionnaire

Each GP has to complete the following questionnaire to verify their eligibility for the study and to collect informations about their POCUS practice :

Question Number	Question	Possible Answer	Answer format
Q1*	Name and Surname	NAME Surname	Free text
Q2*	Email address	/	Free text
Q3*	Phone number	/	10 digits
Q4*	Do you practice general practice?	Yes / No	Single answer question
Q5*	Medical office address	/	Free text
Q6*	Postal Address	/	Free text
Q7*	How many half-days do you practice general practice, including "SOS Médecins" and home visits ?	1-14	Number with 1 or 2 digits
Q8*	Do you work at "SOS Médecins" ?	Yes / No	Single answer question
Q9*	Do you practice POCUS in general practice or at home visits ?	Yes / No	Single answer question
Q10*	How many years have you been practicing ultrasound?	1-99	Number with 1 or 2 digits
Q11*	How many times per consultation day do you use ultrasonography on average ?	1-999	Number with 1 to 3 digits
Q12*	What type of ultrasonography device do you use ?	<ul style="list-style-type: none"> - Don't have any one - Portable device - Ultra portable device - Fixed device - Specify the brand and the model 	Multiples answers question
Q13*	Which kind of probe do you have ?	<ul style="list-style-type: none"> - cardiac/phased array - convex/curvilinear/abdominal - superficial/linear - endovaginal/endocavitary - Other : specify 	Multiples answers question

Q14*	Which anatomical area do you usually explore ?	<ul style="list-style-type: none"> - Abdomen - Muskuloskeletal - Urologic area - Gynecological - Obstetric - Heart - Vascular - Lungs - Thyroid - Tissue - Eyes 	Multiples answers question
Q15*	Have you received ultrasound training?	Yes / No	Single answer question
Q16*	What kind of training have you received ?	<ul style="list-style-type: none"> - Name of degree - Modules followed - Year of obtaining - Number of training hours (theoretical/practice) - Number of supervised exams (if it's relevant) 	Free text
Q17*	Are you a trainer in a course about ultrasonography ?	Yes / No Specify the organization	Single answer question Free text

3.2.4. Supplementary questions

Supplementary questions were asked after discussion with GPs and research team, about :

Q18*	Practice of scheduled ultrasound examinations	Yes / No	Single answer question
Q19*	Frequency of ultrasound billing/fees	All, some of them or none	Single answer question
Q20*	University internship supervisor status	Yes / No Extern, Intern level 1, Intern level 2, intern on a women's or child's health internship	Single answer question Multiple answers question
Q21*	Member of a department of general practice in university	Yes / No	Single answer question

4. Descriptive Statistics

4.1. GPs characteristics

- Gender : Number and proportion de GPs
- Median Age, Interquartiles
- Geographic region of exercise : Number and proportion of GPs
- Setting : Medical office / Home visits / Other (Number and proportion of GPs)
- Experience in ultrasound (years) : median/interquartiles
- "SOS Médecins" network participation : Number and proportion of GPs
- Ultrasound device type : Number and proportion of GP per group (portable, ultra portable and fixed)
- Number of ultrasound devices per GP : médian / interquartile
- Probe type : Number and proportion of GP per group ("superficial/linear", "abdominal/curvilinear", "cardiac/phased-array", "endocavitary", "mixed/multi-probe" and "Other")
- Number of probes per GP : median / interquartile
- Educator of ultrasound in general practice/trainer: Number and proportion of GP
- University internship supervisor status : number and proportion of GP welcoming at least one student (extern, intern level 1, intern level 2, an intern on a women's or child's health internship)
- Faculty/member of a department of general practice in university : number and proportion of GPs
- Practice of scheduled ultrasound examinations : Number and proportion of GPs
- Fees/Billing of ultrasound studies : Number and proportion of GPs per group ("all", "some of them", "none")

4.2. Education/training in ultrasound and applications of POCUS

Visual support : Table

- Number of education/training programs : median/interquartile
- Type of education/training programs : Number and proportion of GP per group :
 - o long (> 1 year), short, others lengths
 - o University degrees, public trainings, private degrees, self study
- Anatomical areas scanned by GPs : Number and proportion per group
- Number of anatomical areas usually scanned : median/interquartile

4.3. Patients's characteristics

Visual support : Flow Chart

- Number of patients eligibles for a POCUS
- Number of patients excluded by GPs, exclusion criteria described
- Number of patients included in the study
- Number of patients excluded after data verification, exclusion of data errors

- Number of patients included in analysis
- Number of patients excluded because of an ultrasound duration of less than 60 seconds
- Number of patients included in “pre-post” analysis
- The difference for age and gender between the excluded patients by GPs according to the exclusion criteria and the included patients in the study will be tested by chi2 test.

Visual support : Table

- Gender : Number and proportion of patients
- Age : médian/interquartile
- Place of performing POCUS : number and proportion of patients per group (“medical office”, “patient’s home”, “other”)
- Geographic region of performing POCUS : Number and proportion of patients per region
- Number of patients included per GP : Median/interquartile

4.4. POCUS’s characteristics

Visual support : Table

- Frequency of POCUS use :
 - o Described according to the distribution, if normal by mean+95%CI if not normal by the median number of POCUS per day / Interquartile,
 - o Proportion of consultations with POCUS during the study
- Indications of POCUS (Q7) : Number and proportion of POCUS per indication
- Duration of POCUS use per consultation (Q15) : Described according to the distribution, if normal by mean+95%CI, if not normal by the median / interquartile
- Certainty of ultrasound findings (Q19) :
 - o Number and proportion of POCUS examinations with at least one certain ultrasound finding
 - o Number and proportion of POCUS examinations with at least one uncertain ultrasound finding
 - o Number and proportion of POCUS examinations with at least one certain positive finding, one certain negative finding, one uncertain positive finding, one uncertain negative finding
- Image relevance (Q18) : Number and proportion of relevant images obtained (total and per organ scanned). Description of reasons for lack of acquisition.

4.5. Anatomical areas scanned

Description of the proportion of POCUS for each kind of anatomical area (Q16).

Visual support : Histogram

Anatomical areas that we plan to distinguish are : Abdominal, urologic, musculoskeletal, pulmonary, cardiac, venous, arterial, thyroid, soft tissues, breast and others.

4.6. Organs scanned

Description of the proportion of organs scanned in POCUS examinations (Q9, Q17).

Visual support : Grouped histogram with organs scanned in abscissa and number of consultations concerned before and after POCUS in ordinate.

Organs scanned will be described in 36 different categories (ref Q9 and Q17).

We will describe the number and proportion of POCUS examinations in which GPs scanned more, fewer or as many organs as initially planned.

4.7. POCUS duration use per consultation

Description of median duration of POCUS exams (Q15).

Visual support : box plot.

We will describe the duration of POCUS by anatomical area for patients having a scan of a single anatomical area. If at least 2 anatomical areas were scanned in the same ultrasound, we will group these patients in a new category called ">1 anatomical area".

The less scanned anatomical areas (less by 5 POCUS performed) will be grouped in a "Others" category.

4.8. Incidental findings

We will describe the incidental findings and their proportion(Q19).

4.9. Diagnostic Hypotheses

We will list the total number of ICPC-2 codes before and after performing POCUS (Q10, 12, 21, 23).

Visual support :

- *Table with number of occurrences for each ICPC-2 code listed during the study, depending on whether it appears as a primary or secondary hypothesis before or after POCUS performing.*
- *Histogram of the most used ICPC-2 codes in the study.*

4.10. Confidence in the final main hypothesis

Number and proportion of POCUS examinations leading to an increase in confidence, to an decrease in confidence or not leading to a change in confidence in the main final hypothesis (Q25).

We will quantify situations where the confidence was decreased, analyse these situations in terms of type of organ scanned, duration of POCUS and change in the diagnostic hypothesis's number before and after POCUS examination.

5. Comparative Statistics

5.1. Change in diagnostic hypotheses

Visual support : Table of consultation number with 1, 2, 3 or 4 diagnostic hypotheses before and after POCUS examination

- Proportion of consultations with a change in the main diagnostic hypothesis
- Proportion of consultation with a global change in diagnostic hypotheses (Q20)
- Number of ICPC-2 code classed as “symptom” before POCUS, and number of classed as “symptom” after POCUS

A global modification of diagnostic hypotheses corresponds to a modification, a removal or an addition of a diagnostic hypothesis after POCUS, or a change in the main hypothesis.

We will study the relationship between the reduction of the number of diagnostic hypotheses and increase in the confidence with a Chi2 test if the numbers in each group are greater than 5. If the number in each group is lower than 5, we will use a Fisher test.

5.2. Change in care pathway/referral plan

Number and proportion of consultation with a change in care pathway / referral plan (Q26).

Visual support : Table (continuation of the table 5.1)

- Number and proportion of consultations with a referral for each category of referral before and after POCUS examination (Q13, Q27)
- Change in referral to emergency departments (Relative risk, 95% CI, Mac Nemar test)

We will group referrals to hospital and specialist in semi-emergency in a category “semi-urgent referral”, and hospital and specialist in the context of non-emergency in a category “non-urgent referral”.

5.3. Change in imaging prescription

We will consider there is a change in imaging prescription if there is a prescription of different imaging modalities before and after POCUS.

Visual support : Table (continuation of the table 5.1)

- Number and proportion of consultations with a prescription of each kind of imaging modality before and after POCUS examination (“Radiography”, “Echography”, “IRM”, “TDM”, “Other imaging”) (Q13, Q27)
- Change in imaging prescription, regardless of the type of imaging (Relative risk, 95% CI, Mac Nemar test)

Visual support : Table

- Number and proportion of consultations with an increase in imaging prescription after POCUS examination, and a decrease in imaging prescription for each imaging modality.

- Number and proportion of consultations with a final imaging prescription while none were prescribed initially.
- Number and proportion of consultations with an initial imaging prescription while none were prescribed finally.

5.4. Change in treatment plan

Number and proportion of consultations with a change in treatment plan (Q28).

Visual support : Table (continuation of the table 5.1)

- Number and proportion of consultations with a prescription for each treatment category before and after POCUS examination (Q14, Q29)
- Change in prescription of overall treatment (relative risk, 95% CI, Mac Nemar test)

Non-medical treatments included physiotherapist, podiatrist and osteopath.

5.5. Change according to anatomical areas

Number and proportion of consultations changed according to anatomical areas :

- Change in main diagnostic hypothesis
- Global change in diagnostic hypotheses
- Change in imaging prescription
- Change in treatment plan
- Change in care pathway / referral plan
- Global change in patient care

Visual support : Table.

We will describe the change in patient care by anatomical area for patients having a scan of a single anatomical area. If at least 2 anatomical areas were scanned in the same ultrasound, we will group these patients in a new category called ">1 anatomical area".

5.6. Global change in patient care

We will consider a global change if there was a change in the main hypothesis, a global change in diagnostic hypotheses, a change in treatment plan, in patient's orientation plan or in imaging or exams prescription.

Visual support : Table (continuation of the table 5.1)

Number and proportion of consultations with a global change in patient care.

For all comparative analyses, we will consider consultations with a measured POCUS duration greater than 60 seconds.