

Title	Survey of adult and paediatric rheumatology patients suggests information about COVID-19 vaccination will aid uptake.
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Key message	Development of clear, concise, accessible information about COVID-19 vaccination for rheumatology patients will aid uptake.

Dear Editor,

Survey of adult and paediatric rheumatology patients suggests information about COVID-19 vaccination will aid uptake.

The COVID-19 European Patient Registry (EPR) is a longitudinal study⁽¹⁾ developed by parents of children and young people representing the European Network for Childhood Arthritis (ENCA), with support and involvement from individuals and organisations across Europe, including adult patients and the Paediatric Rheumatology European Society (PReS); a copy of the survey is provided in the supplementary document. Adult patients with rheumatic, autoimmune and autoinflammatory conditions and parents of paediatric patients completed weekly surveys from April to December 2020. A total of 4,336 participants from 58 countries took part in the EPR and 2.9% of each cohort have been diagnosed with COVID-19, with only 10 adults and 1 child admitted to hospital.

In December 2020, participants were asked "When a vaccine against COVID-19 is available, will you have the vaccine when you are offered it?" They were also asked if they have had the seasonal flu vaccine and, in both cases, invited to explain why not, if applicable, through free-text questions.

Overall, 1,505 adult and 140 paediatric patients answered these questions. Of them, 87% of adults and 66% of children responded that they would have the COVID-19 vaccine. A further 11% of adults and 31% of children were unsure, leaving just 2% and 3% respectively who do not intend to have the vaccine when it is offered.

An analysis of reasons for not having the COVID-19 vaccine offers some insight into patient motivations. Whilst some presented clear medical reasons for not having the vaccine (28% of adult and 28% of paediatric respondents answering this question), such as prior anaphylaxis, currently breastfeeding, or direct clinical advice, others indicated a lack of information was preventing them from currently accepting the vaccine (51% adults, 22% paediatric). This lack of information included concerns about possible medication contraindications, safety and efficacy for patients with autoimmune conditions, and side-effects. Others misunderstood the development protocol for the vaccine or its purpose, leading to lack of trust (18% adults, 22% paediatric).

Parents of children within the EPR also expressed concerns about suitability of the vaccine for under-16-year-olds (28% of parents responding to this question), but were broadly supportive of having a vaccine once approved for their use.

We recognise that some patients have decided against having the vaccine for ethical reasons, and a very small number due to conspiracy theories or misrepresentation of the dangers of COVID-19 infection. However, these represent a very small minority of patients within our cohort.

Table 1 shows the broad themes and specific concerns reported by participants, along with an estimation of the benefit of directed guidance for these patient groups.

Theme *	Specific concerns raised	Likely outcome of information provision
Medical 28% adults 28% paediatric	<ul style="list-style-type: none"> • Anaphylaxis or allergies to previous vaccines and medications • Currently pregnant or breastfeeding • Advised by doctor not to have vaccine 	Due to legitimate health issues, this group is unlikely to accept vaccination
Information 51% adults 22% paediatric	<ul style="list-style-type: none"> • Lack of information on medication contraindications with immune-modifying and anti-rheumatic drugs • Lack of information on safety for patients with autoimmune diseases • Lack of long-term safety and efficacy data • Concern that vaccine is unsafe or untested • Concerns about side-effects • Concerns about whether it will be effective with the current new strain 	Clear, concise and accessible information is likely to increase vaccination uptake and reduce direct calls to rheumatology centres
Understanding 6% adults 11% paediatric	<ul style="list-style-type: none"> • Use of live viruses • Concerns about live bacteria • Questions about whether patients who have previously had COVID-19 need the vaccine • Misunderstanding of how vaccines work, particularly mRNA vaccines 	Clear, concise and accessible information is likely to increase vaccination uptake and reduce direct calls to rheumatology centres
Trust 12% adults 11% paediatric	<ul style="list-style-type: none"> • Lack of trust in government • Lack of trust in vaccine development process 	Unbiased information, may lead some to choose to vaccinate
Ethical 1% adults 0% paediatric	<ul style="list-style-type: none"> • Ethical concerns regarding animal testing in vaccine development 	Some patients may choose to receive the vaccine
Children 28% paediatric	<ul style="list-style-type: none"> • Suitability of vaccines for under-16-year-olds 	When vaccines are approved and available for paediatric use, uptake is likely to be high
Conspiracy 2% adults 0% paediatric	<ul style="list-style-type: none"> • Very few cited conspiracy theories • Belief that COVID-19 is not severe enough to warrant vaccination 	Vaccination unlikely amongst this group, although clear concise information may support informed choice

Table 1. Themes and specific concerns raised about COVID-19 vaccination by adult patients and parents of paediatric patients with rheumatic, autoimmune and autoinflammatory conditions, along with the anticipated benefit of provision of clear, concise, accessible information from a trusted source. * Percentages indicate proportion of free-text comments representing this topic from those adult and paediatric respondents who gave a comment. Paediatric surveys completed by parents of children under the age of 16. Percentages are indicative, and not necessarily representative of all patients.

It is important that clear information is prepared, agreed and shared promptly through national and international professional bodies, and through clinical teams. Unlike current generic advice, this should address the specific concerns raised by

rheumatology patients through the EPR. It is our opinion that clear, concise and accessible information from a trusted source will support and encourage many of these patients to make an informed choice about COVID-19 vaccination, leading to an increase in the uptake of the vaccine amongst these at-risk patients. The PRES website has guidelines for clinicians(2). Ultimately, it will also reduce the burden on individual rheumatology teams, as fewer patients will contact them for vaccine advice. We also urge that the stage 2/3 trials for the COVID-19 vaccines amongst children and young people be accelerated.

The authors declare no conflicts of interest.

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Data available with a request.

References

1. Proceedings of the 26th European Paediatric Rheumatology Congress: part 2. *Pediatr Rheumatol*. 2020 Oct 28;18(2):82.
2. PReS -- English: Guidelines and Recommendations [Internet]. [cited 2021 Jan 18]. Available from: <https://www.pres.eu/clinical-affairs/guidelines.html>



The COVID-19 European Patient Registry

Introduction to the European Patient Registry surveys

The surveys that follow are those completed by adults taking part in the European Patient Registry. The questions asked to parents of children and young people within the paediatric Registry were amended to refer to 'your child' in place of 'you' but otherwise included the same questions and response categories (the exception being the list of rheumatological conditions, for which different response categories were provided; this is shown in this document).

Within this document, the following conventions apply:

- [Select one] Completion instructions in purple, square brackets.
- [go to ...] Routing instructions in red, square brackets.
- (Added) Questions added after initial launch are indicated in blue italics, bracketed.

Part 1: Initial survey completed by participants when signing-up to join the European Patient Registry

Introductory text and consent statement

The COVID-19 (Coronavirus) pandemic has quickly infected hundreds of thousands of people worldwide. While many people with COVID-19 infections have mild or no symptoms, a significant proportion of patients can become quite ill. At this time, little is known about how patients with rheumatic diseases or autoimmune conditions, many of whom use medications and drugs that suppress the immune system, are affected by the virus.

You will be able to join the study by completing this initial survey that will ask about your medical history and medications that you take. Then, every week we will ask you to fill in a short survey to note any symptoms that you may have developed and whether you have been diagnosed with COVID-19. If so, we will ask you for more information about how you were treated and how you recovered from the disease.

We need to collect your email address so that we can send you the follow-up surveys. However, your email address is removed from the data before it is analysed. We will never share your email address with anyone else.

Please do not submit any other personal information (such as your name, address or contact details) with this form. You do not have to complete the form and are free to leave the study at any time. Any treatment or support you are receiving will not be affected if you choose not to take part. Information collected will be analysed anonymously by our research consortium. Your anonymous data, along with that of other participants, will be analyzed together to improve our understanding of how COVID-19 affects patients with rheumatic and autoimmune diseases. Your anonymous data will be shared with researchers to support the analysis of the results. Individual participants will never be identified. We plan to present the results of our study in various medical and scientific conferences, as well as publishing our conclusions in various medical journals.

A copy of our privacy notice can be found on our website [\[link\]](#).

In this survey we ask about 'rheumatological conditions'. This also includes autoinflammatory diseases and autoimmune conditions.

The information you provide in this survey is not shared with your doctor or healthcare provider. If you are concerned about your symptoms or health, you must seek advice from your doctor.

1/01 I'm ready

I have read the information above and am ready to begin.

1/02 How old are you?

Please give your age in years.

1/03 Are you...

[Select one]

- Male
- Female
- Prefer not to say
- Non-binary

1/04 In which country do you live?

[Select one]

- Albania
- Andorra
- Armenia
- Austria
- Azerbaijan
- Belarus
- Belgium
- Bosnia and Herzegovnia
- Bulgaria
- Croatia
- Cyprus
- Czechia
- Denmark
- Estonia
- Finland
- France
- Georgia
- Germany
- Greece
- Hungary
- Iceland
- Ireland
- Israel
- Italy
- Kazakhstan
- Kosovo
- Latvia
- Liechtenstein

- Lithuania
- Luxembourg
- Malta
- Moldova
- Monaco
- Montenegro
- Netherlands
- North Macedonia (formerly Macedonia)
- Norway
- Poland
- Portugal
- Romania
- Russia
- San Marino
- Serbia
- Slovakia
- Slovenia
- Spain
- Sweden
- Switzerland
- Turkey
- Ukraine
- United Kingdom (UK)
- Vatican City (Holy See)
- Other (Outside Europe)

If you have selected 'other', please tell us which country you live in. [_____]

1/05 How tall are you (approximately)
[_____]

1/06 What units have you given your height in?
[Select one]

- Metres (cm)
- Feet and inches (ft/in)

1/07 What is your weight (approximately)
[_____]

1/08 What units have you given your weight in?
[Select one]

- Kilograms (kg)
- Stone and pounds
- Pounds (total)

1/09 Do you smoke?
[Select one]

- Yes - I am a current smoker [\[go to question 1/10\]](#)
- No - I used to smoke but do not now [\[go to question 1/12\]](#)
- No - I have never smoked [\[go to question 1/13\]](#)

1/10 What type of cigarettes do you use?

[Select all that apply]

- Regular cigarettes
- Cigar
- Pipe
- Vape
- e-cigarettes
- Other... [_____]

1/11 How many cigarettes do you smoke per day?

[_____]

[Go to question 1/13]

1/12 When did you stop smoking?

[Select one]

- Within the last six months
- Within the past year
- 1-2 years ago
- 3-5 years ago
- 5-10 years ago
- More than 10 years ago

[Go to question 13]

1/13 We know that some people have more than one rheumatological condition. This form has boxes to record up to five diagnoses. If you need more space, use the box at the end of this section. By 'rheumatological condition', we also include autoinflammatory diseases and autoimmune conditions.

Which of these have you been diagnosed with?

[Select one]

- ANCA-associated vasculitis
- Any other vasculitis including Kawasaki disease or if you are not sure which type
- Anti-phospholipid antibody syndrome
- Autoinflammatory syndrome disease (including, Familial Mediterranean Fever, TRAPS, CAPS, PFAPA) [please specify]
- Axial spondyloarthritis (including ankylosing spondylitis)
- Other spondyloarthritis (including reactive arthritis)
- Behcet's disease
- Chronic recurrent multifocal osteomyelitis (CRMO)
- Giant cell arteritis (also called Temporal arteritis)
- IgG4-related disease
- Inflammatory myopathy (also called myositis, dermatomyositis, polymyositis)
- Systemic juvenile idiopathic arthritis
- Juvenile idiopathic arthritis, not systemic
- Mixed connective tissue disease (MCTD)
- Polymyalgia rheumatica
- Psoriatic arthritis
- Rheumatoid arthritis

- Other inflammatory arthritis
- Sarcoidosis
- Sjogren's syndrome
- Still's Disease
- Systemic lupus erythematosus (lupus)
- Systemic sclerosis (systemic or limited, also known as scleroderma)
- Localized scleroderma (also known as morphea or morphea)
- Undifferentiated connective tissue disease (UCTD)
- None
- Other [please specify below]

1/14 If 'other', what condition have you been diagnosed with?
[_____]

1/15 In which year was this diagnosed?
[_____]

1/16 Do you have another rheumatological condition?
[Select one]

- Yes [\[go to question 13\]](#)
- No [\[go to question 17\]](#)

1/17 Have you ever had macrophage activation syndrome (MAS)?
[Select one]

- Yes
- No
- Not sure

1/18 Which of the following medications have you taken in the past MONTH?
[Select all that apply]

- Steroids (such as prednisone, methylprednisolone, prednisolone)
- Antimalarials (including hydroxychloroquine/Plaquenil, chloroquine)
- IL-6 inhibitors (including Tocilizumab/Actemra, Sarilumab/Kevzara)
- TNF-inhibitors (including Infliximab/Remicade, Etanercept/Enbrel, Adalimumab/Humira/Amgevita, Golimumab/Simponi, Certolizumab/Cimzia, and biosimilar versions eg Amgevita for Adalimumab, Benepali for Etanercept and others)
- IL-1 inhibitors (including Anakinra/Kineret, canakinumab/Ilaris, rilonacept/Arcalyst)
- Methotrexate / Trexxal (including brands such as Metoject, Methofill, Ledertrexate, and Emthexate)
- Leflunomide/Arava
- Rituximab/Rituxan (including biosimilar version)
- JAK inhibitors (including tofacitinib/Xeljanz, baricitinib/Olumiant, upadacitinib/Rinvoq)
- Abatacept/Orencia
- IL-17 inhibitors (including Secukinumab/Cosentyx, Ixekizumab/Taltz)
- IL-12/23 inhibitors (including ustekinumab/Stelara, guselkumab/Tremfya)

- Sulfasalazine/Azulfidine
- Azathioprine/Imuran / 6-MP/mercaptopurine
- Mycophenolate mofetil/CellCept / mycophenolic acid/Myfortic
- Belimumab/Benlysta
- Cyclophosphamide/Cytoxan
- Cyclosporine/Neoral/Sandimmune
- Tacrolimus/Prograf
- Apremilast/Otezla
- Thalidomide/Thalomid / Lenalidomide/Revlimid
- Proton pump inhibitors (such as lansoprazole)
- Anti-emetics or anti-nausea (such as ondansetron, stemetil, phenergan)
- Folic acid
- Non steroidal anti-inflammatory drugs (NSAID) such as ibuprofen, Advil, naproxen, Aleve, indomethacin, Indocin, ibuprofen, Nurofen, Junifen, Brufen, diclofenac, Voltarol, meloxicam, celecoxib, etoricoxib)
- Paracetamol (also called Acetaminophen or Tylenol)
- Colchicine
- ACE inhibitors (such as lisinopril, captopril, ramipril)
- None
- Not sure
- Other... [_____]
-

1/19 If you have taken any steroids (such as cortisone, glucocorticoids or corticosteroid) in the past month, what is the name of the steroid medication?
[_____]

1/20 If you have taken any steroids (such as cortisone, glucocorticoids or corticosteroid) in the past month, what dose have you been taking?
[_____]

1/21 If you have taken any steroids (such as cortisone, glucocorticoids or corticosteroid) in the past month, how often have you been taking it?
[_____]

1/22 Have you had rituximab (Rituxan) in the past 6 months?

- Yes
- No
- Not sure

1/23 Do you have any of the following medical conditions?

[Select all that apply]

- Diabetes (type 1 or type 2)
- Heart disease (including heart attack and congestive heart failure)
- High blood pressure
- Pulmonary hypertension (high blood pressure in the lungs)
- Emphysema
- Asthma
- Chronic obstructive pulmonary disease (COPD)
- Other lung disease (including interstitial lung disease)

- Kidney disease
- Cancer
- History of organ transplant
- Pregnancy (currently pregnant)
- Post-partum (you gave birth within the past 6 weeks)
- Immunodeficiency, including HIV
- Liver disease
- Chronic neurological or neuromuscular disease
- IBD
- Trisomy 21
- None
- Other... [_____]

[\[Go to Part 2, weekly survey\]](#)

Part 2: Weekly survey completed by participants each week

This part of the survey asks for details of your symptoms from Monday to Sunday of last week. For symptoms that are part of your normal medical condition, please only indicate if you have experienced a worsening in your symptoms. You will receive this part of the survey each week whilst you are part of the patient registry.

2/01 In the past week, have you experienced any of the following signs or symptoms?

[\[Select each day where you experienced each symptom\]](#)

- Fever (measured temperature above 38C)
- Cough
- Shortness of breath
- Sore throat
- Blocked nose
- Running nose
- Red eyes
- Headache
- Joint pain
- Muscle pain or aches
- Fatigue (tiredness)
- Chills
- Nausea
- Vomiting
- Diarrhoea
- Loss of taste or smell
- Sore mouth (*Added 25 May 2020*)
- Rash (*Added 25 May 2020*)
- Other (specify below)
- None
- If you have chosen 'other' symptom, please tell us what it is here:
[_____]

2/02 In the past week, have you been diagnosed with any of these?

[\[Select one\]](#)

- COVID-19 (novel coronavirus) [\[go to question 2/03\]](#)

- Influenza (seasonal flu) [\[go to question 2/09\]](#)
- Nonspecific viral illness [\[go to question 2/09\]](#)
- Strep throat [\[go to question 2/09\]](#)
- Pneumonia [\[go to question 2/09\]](#)
- None of these [\[go to question 2/09\]](#)

2/03 When were you diagnosed with COVID-19?

Please give date as accurate as possible.

[dd, mm, yyyy]

2/04 How were you diagnosed with COVID-19?

[\[Select one\]](#)

- Self-diagnosis based on symptoms
- A doctor diagnosed me based on my symptoms
- A doctor diagnosed me based on positive test results

2/05 Where was the diagnosis of COVID-19 made?

[\[Select one\]](#)

- Home or standalone testing
- Nursing home or assisted living facility
- Outpatient clinic
- Emergency Department of hospital
- Hospital, where I was staying as an inpatient
- Telehealth/telemedicine
- Other... [_____]

2/06 Have you received any of the following medications for your COVID-19 infection?

Not everyone will receive the same medication, and not everyone will need medication. We want to understand which medications you may have had so we can see how they affect patients. If you aren't sure which type of medication you have been given, please type the name from the label into the Other box).

[\[Select all that apply\]](#)

- No treatment
- Paracetamol
- Non steroidal anti-inflammatory drugs (NSAID) such as ibuprofen, Advil, naproxen, Aleve, indomethacin, Indocin, nurofen
- Anti-viral drugs (e.g. lopinavir-ritonavir/Kaletra, /remdesivir)
- Anti-malarial drugs (e.g. chloroquine, hydroxychloroquine, Plaquenil)
- IL-1 inhibitors (including Anakinra/Kineret, canakinumab/Ilaris, rilonacept/Arcalyst)
- Il-6 inhibitors (e.g. Tocilizumab/Actemra, sarilumab/Kevzara)
- Bevacizumab/Avastin
- JAK Kinase inhibitors (including tofacitinib/Xeljanz, baricitinib/Olumiant, upadacitinib/Rinvoq)
- Serpin inhibitors
- Ciclesonide
- Plasma from recovered patients

- Not sure
- Other... [_____]

2/07 How have things turned out?

[Select one]

- I was not hospitalized, and could carry on as normal
- I was not hospitalized, but had some limitation on activities due to my illness
- I was hospitalized, but did not require supplemental oxygen
- I was hospitalized, and did need supplemental oxygen
- I was hospitalized, and put on non-invasive ventilation or high flow oxygen devices (eg. CPAP)
- I was hospitalized, and put on invasive mechanical ventilation (endotracheal tube) or ECMO
- Other

2/08 Please tell us about any other assessments, tests or scans that you have had due to your COVID-19. If you are able to, please tell us what was done and what the results were.

This can include x-rays, MRI scans, ultrasound scans, and assessments by a doctor.

(Added 25 May 2020)

[_____]

2/09 What methods have you been using over the past week to protect yourself from COVID-19?

[Select all that apply]

- Self-isolation (no symptoms of infection, but am choosing to stay at home and avoiding social contact)
- Social distancing (avoiding crowds and large groups of people)
- Quarantine (May have been exposed to the virus but not yet symptomatic, staying home and avoiding others)
- Isolation (thought to be infected and staying home, avoiding contact with others as much as possible)
- None
- Other... [_____]

2/10 If you have been in quarantine, who made the decision for quarantine?

[Select one]

- I did
- My doctor advised me to
- It was imposed on me by the authorities (city/state/country/health service)
- Not applicable - I have not been in quarantine

2/11 In the past week, have you taken any doses of the following medication?

[Select all that apply]

- Non steroidal anti-inflammatory drugs (NSAID) such as ibuprofen, Advil, naproxen, Aleve, indomethacin, Indocin, nurofen, meloxicam, celecoxib, etoricoxib)
- Paracetamol (also called Acetaminophen or Tylenol)
- None

2/12 In the past week, have you changed your medication?

Include where you have reduced or increased or changed your medication, or stopped taking a medication, delayed taking a dose, or started a new one.

[Select one]

- Yes [go to question 2/13]
- No [go to question 2/18]

2/13 What have you changed and how?

[_____]

2/14 Have you stopped taking any of your usual medication?

[Select one]

- Yes [go to question 2/15]
- No [go to question 2/18]

2/15 If you have stopped taking any medication, why did you stop taking the medication ?

[Select all that apply]

- I finished the prescribed course
- There was a shortage of medication at the pharmacy
- My rheumatologist or doctor advised me to stop
- I decided to stop to avoid immunosuppression
- It was no longer needed
- I have an infection
- I cannot access the hospital or clinic where I have the drug administered (for example, injections or infusions)
- Other... [_____]

2/16 Did you discuss these changes with your rheumatologist or doctor?

[Select one]

- Yes
- No

2/17 Do you (and your rheumatologist or doctor) intend to resume the same treatment when it is possible?

[Select one]

- Yes
- No

2/18 Have you been in contact with someone who is diagnosed with or suspected to have coronavirus?

[Select one]

- Yes
- No
- Not sure

- 2/19 On a scale of 0 to 10 how worried are you about coronavirus affecting you?
[Select one]
0 – Not at all worried
10 - Extremely worried
- 2/20 How have you communicated with your rheumatologist or doctor in the past 14 days?
[Select all that apply]
 I do not have a rheumatologist
 I have not needed to communicate with them
 I contacted them by phone call
 I contacted them by email or patient portal
 I contacted them by Telemedicine / Videoconference
 I visited them at the hospital or clinic
 Other... [_____]
- 2/21 In the last 14 days, how well has your rheumatic or autoinflammatory disease or autoimmune condition been controlled?
[Select one]
0 – Very poorly
10 – Very well
- 2/22 In the past week, have you used a face mask or face covering when leaving your home?
Please try to think about every time you have left your home, for any reason, in the past week. This includes exercise, shopping, work, school, hospital or doctor visits and any other reason. A face mask or face covering is any mask or covering that covers both your nose and mouth.
(Added 20 July 2020)
[Select one]
 I have not left my home at all in the past week.
 When I have left my home this week, I have always stayed outdoors and have not worn a face mask or face covering.
 Yes, I have used a face mask or face covering every time I left my home.
 Yes, I have used a face mask or face covering every time when I was going to be indoors or in crowded places.
 Yes, I have used a face mask or face covering, but not every time when I was going to be indoors or in crowded places.
 No, I have not used a face mask or face covering when leaving my home this week.
- 2/23 In the past week, on how many days has your child attended school or college on site?
(Added 31 August 2020, paediatric survey only)
[Select one]
[0 – 15]
- 2/24 Did you have the seasonal flu vaccine this year?

(Added 7 December 2020)

[Select one]

- Yes
- No

2/25 If no, why did you not have the vaccine?

(Added 7 December 2020)

[_____]

2/26 When a vaccine against COVID-19 is available, will you have the vaccine when you are offered it?

(Added 7 December 2020)

[Select one]

- Yes
- No
- Not sure

2/27 If no, why will you not have the COVID-19 vaccine?

(Added 7 December 2020)

[_____]

2/28 Since March, approximately how many medical appointments have you had through telemedicine (including telephone and video calls)?

(Added 7 December 2020)

[Select one]

[0 – 15]

2/29 Since March, approximately how many medical appointments have you attended in person (at a hospital, clinic or surgery)?

(Added 7 December 2020)

[Select one]

[0 – 15]

2/30 If you have any comments about the use of telemedicine, please tell us here (whether you preferred telemedicine, or prefer face-to-face appointments, or some of the good things about telemedicine, or any problems you faced with it).

(Added 7 December 2020)

[_____]

2/31 Please use the space below to tell us anything else that you would like us to know about.

Please do NOT give any personal information or contact details. Please note that we are NOT able to respond to your comments. If you have any concerns about your health, please speak with your doctor or healthcare professional.

(Added 25 May 2020, English Language survey only)

[_____]