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Paulina Małgorzata Malarkiewicz

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„Nowe wyzwania opieki perinatalnej podczas pandemii COVID-19”

„New perinatal care challenges during the COVID-19 pandemic”

Praca wykonana w Katedrze Ginekologii i Położnictwa

Promotor: dr hab. n. med. Tomasz Waśniewski, prof. UWM - Uniwersytet Warmińsko-Mazurski w Olsztynie

Promotor pomocniczy: dr Stanisław Maksymowicz - Uniwersytet Warmińsko-Mazurski w Olsztynie

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PUBLIKACJE STANOWIĄCE ROZPRAWĘ DOKTORSKĄ

Niniejsza rozprawa doktorska pt. „*Nowe wyzwania opieki perinatalnej podczas pandemii COVID-19*", oparta jest o monotematyczny zbiór artykułów (3 artykuły oryginalne), opublikowanych w międzynarodowych czasopismach naukowych, indeksowanych w bazie PubMed oraz znajdujących się na liście Journal Citation Reports (Thomson Reuters).
Łączna wartość „Impact Factor" dla cyklu wymienionych prac wynosi 10,2 oraz 320 punktów Ministerstwa Nauki i Szkolnictwa Wyższego (według „listy A").

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- *Mother's Loneliness: Involuntary Separation of Pregnant Women in Maternity Care Settings and Its Effects on The Experience of Mothers during the COVID-19 Pandemic.*
  Malarkiewicz, P., Maksymowicz, S., Libura, M.
  International Journal of Environmental Research and Public Health, 2022, 19(9), 5081

- *COVID-19 Vaccination Status among Pregnant and Postpartum Women—A Cross-Sectional Study on More Than 1000 Individuals.*
  Nowacka, U., Malarkiewicz, P., Sierdzinski, J., Januszaniec, A., Kozłowski, S., Issat, T.
  Vaccines, 2022, 10(8), 1179

- *Intrahepatic Cholestasis of Pregnancy during COVID-19 Pandemic.*
  Malarkiewicz, P., Nowacka, U., Januszaniec, A., Mankiewicz., Kozłowski, S., Issat, T.
  Medicina (Lithuania), 2024, 60(4), 676

STRESZCZENIE

Badania zawarte w serii artykułów podkreślają, w jaki sposób pandemia wpłynęła na zdrowie i samopoczucie kobiet w ciąży, pokazując potrzebę dostosowania praktyk medycznych do wyzwań spowodowanych globalnym kryzysem zdrowotnym.

Badanie przeprowadzone na temat samotności kobiet w ciąży spowodowanej przymusową separacją od partnerów w placówkach opieki zdrowotnej podczas pandemii COVID-19 wykazało znaczące negatywne skutki psychologiczne takiej separacji. Analiza danych ujawniła znaczny wzrost poziomu lęku i stresu wśród respondentów, co podkreśla krytyczną potrzebę przemyślanej modyfikacji procedur medycznych i wsparcia psychologicznego ciężarnych w trakcie globalnego kryzysu zdrowotnego. Kolejne badanie dotyczące akceptacji szczepień przeciwko COVID-19 wśród kobiet w ciąży i po porodzie wykazało, że wyższe wykształcenie i pozytywne interakcje z pracownikami służby zdrowia zwiększyły prawdopodobieństwo wyrażenia zgody na szczepienie, podczas gdy głównym powodem odmowy były obawy dotyczące bezpieczeństwa szczepionek. Wyniki te pokazują znaczenie edukacji zdrowotnej i komunikacji w promowaniu zdrowia publicznego. Badanie analizujące występowanie wewnątrzwątrobowej cholestazy ciążowej (ICP) podczas pandemii wykazało spadek liczby łagodnych przypadków ICP, co może wskazywać na bariery w dostępie do opieki medycznej i zmiany w procedurach diagnostycznych podczas pandemii. Stabilność wskaźnika ciężkich przypadków ICP podkreśla potrzebę utrzymania wysokiego poziomu czujności klinicznej w zarządzaniu ryzykiem dla zdrowia matki i dziecka w przyszłych pandemiach.

SŁOWA KLUCZOWE: COVID-19, ciąża, lęk, opieka okołoporodowa, szczepienia, wewnątrzwątrobowa cholestaza ciążowa

SUMMARY

The research included in the series of articles highlights how the pandemic has affected the health and well-being of pregnant women, showing the need to adapt medical practices to the challenges brought about by the global health crisis.

A study conducted on the loneliness of pregnant women caused by forced separation from their partners in healthcare facilities during the COVID-19 pandemic found significant negative psychological effects of such separation. Data analysis revealed a substantial increase in the level of anxiety and stress among respondents, which highlights the critical need for thoughtful modification of medical procedures and psychological support for mothers during the global health crisis. Another study on accepting COVID-19 vaccinations among pregnant and postpartum women revealed that higher education and positive interactions with healthcare workers increased the likelihood of consent to vaccination. At the same time, the main reason for refusal was concerns about vaccine safety. These results demonstrate the importance of health education and communication in promoting public health. A recent study analyzing the occurrence of intrahepatic cholestasis of pregnancy (ICP) during the pandemic showed a decrease in the number of mild cases of ICP, which may indicate barriers to access to medical care and changes in diagnostic procedures during the pandemic. The stability of the rate of severe ICP cases highlights the need to maintain a high level of clinical vigilance in the management of maternal and child health risks in future pandemics.

KEY WORDS: COVID-19, pregnancy, anxiety, perinatal care, vaccinations, intrahepatic cholestasis of pregnancy

WSTĘP

Definicja problemu – opieka nad kobietą w okresie okołoporodowym

W Polsce opieka nad kobietą w okresie ciąży i połogu regulowana jest Rozporządzeniem Ministra Zdrowia z dnia 16 sierpnia 2018 r. (ROZPORZADZENIE MINISTRA ZDROWIA Z DNIA 16.08.2018 w sprawie standardu opieki okołoporodowej Dz.U. 2018, poz. 1756), które weszło w życie 1 stycznia 2019 r. Rozporządzenie wprowadziło zmiany mające na celu poprawę jakości opieki okołoporodowej w Polsce, zdecydowanie kładąc nacisk na indywidualne podejście do pacjentki oraz zapewnienie jej godności i bezpieczeństwa. Dodatkowo kwestie standardów medycznych regulują liczne rekomendacje wydawane regularnie przez Polskie Towarzystwo Ginekologów i Położników.

Pandemia COVID-19 została oficjalnie ogłoszona przez Światową Organizację Zdrowia (WHO) 11 marca 2020 roku. Choroba wywołana przez koronawirusa SARS-CoV-2 zaczęła rozprzestrzeniać się na początku listopada 2019 roku w mieście Wuhan w Chinach. Pierwszy przypadek w Polsce został potwierdzony 4 marca 2020 roku. (*Coronavirus Disease (COVID-19) Pandemic*, n.d.) Do połowy lipca 2024 roku odnotowano ponad 700 mln przypadków zakażenia wirusem SARS-CoV-2 w 192 państwach i terytoriach, ponad 675 mln ozdrowień oraz ponad 7 mln zgonów. (COVID - Coronavirus Statistics - Worldometer, 5.09.2024 Badania naukowe dowiodły, że ciąża znacząco zwiększyła ryzyko ciężkiego przebiegu COVID-19. Ciężarne zarażone COVID-19 były aż 20 razy bardziej narażone na zgon niż te, które nie zaraziły się wirusem (Villar et al., 2021).

Pandemia COVID-19, wywołana przez wirusa SARS-CoV-2, narzuciła bezprecedensowe wyzwania całemu systemowi opieki zdrowotnej. Wywarła znaczący wpływ na globalne systemy opieki zdrowotnej, wprowadzając liczne zmiany w prawie każdym obszarze medycyny. Szczególnie dotkliwie pandemia odcisnęła swoje piętno właśnie na opiece perinatologicznej, która zajmuje się zdrowiem ciężarnej oraz płodu. Zarówno ograniczenia w dostępie do usług medycznych, jak i obawy przed zarażeniem w placówkach medycznych, wpłynęły na zmiany w procedurach diagnostycznych, terapeutycznych oraz w procesie podejmowania decyzji przez pacjentki i personel medyczny. Pandemię można było uznać za nową i niepewną sytuację dla większości społeczeństwa. Żaden rząd ani system opieki zdrowotnej, nie był przygotowany na taki kryzys. Zagrożenie dla życia i/lub zdrowia związane z nową chorobą zakaźną jest i było głównym czynnikiem stresującym. Same środki mające na celu złagodzenie ryzyka zakażenia okazały się być dodatkowym obciążeniem dla pacjentek. Na

początku pandemii w 2020 r. urzędnicy opieki zdrowotnej w Polsce zasugerowali, że wskazane jest odłożenie wszelkich planów powiększenia rodziny ze względu na potencjalne negatywne skutki COVID-19 dla ciąży, a także ograniczenia w funkcjonowaniu szpitali i oddziałów położniczych. Polskie Towarzystwo Położników i Ginekologów, kierując się międzynarodowymi wytycznymi (Benski et al., 2020), zaleciło wstrzymanie porodów rodzinnych z dniem 20 marca 2020 r. Zawieszono również możliwość obecności partnera podczas badań USG kobiety ciężarnej (Stanowisko Prezydium PTGiP Odnośnie Interpretacji Zarządzenia NFZ Dotyczącego Porodów Rodzinnych | Ptgin.Pl, 2020.). Jednakże wiele ciąż było już w toku, nie wspominając o tym, że wstrzymanie prokreacji w całej populacji jest i było niemożliwe. Dlatego opieka prenatalna musiała funkcjonować w rzeczywistości zmieniających się wytycznych i zmieniających się obostrzeń pandemicznych.

CEL I ZAKRES BADAŃ

Badania ujęte w cykl prezentowanej pracy podkreślają, jak pandemia wpłynęła na zdrowie i dobrostan ciężarnych, ukazując potrzebę dostosowania praktyk medycznych do wyznawań jakie niesie globalny kryzys zdrowotny. Zaburzenia zdrowia psychicznego stają się szczególnie trudne, gdy sytuacje zagrażające życiu i/lub zdrowiu występują na szerszej płaszczyźnie społecznej, co niewątpliwie miało miejsce w przypadku pandemii COVID-19 (Platto et al., 2021). Kobiety będące aktualnie w wieku rozrodczym nie pamiętają wcześniejszych pandemii z XX wieku. A te nowsze miały ograniczony wpływ na odbiór społeczny w większości krajów. Globalna pandemia zespołu ostrej niewydolności oddechowej (SARS) w 2002–2003 r. była pierwszą w XXI wieku (Platto et al., 2021). Jednak, ponieważ obejmowała ona tylko mieszkańców krajów azjatyckich, reszta świata była głównie obserwatorami. Ponadto pandemia SARS nie wywołała tak dużego strachu i nie odnotowała tak wielu zgonów jak pandemia COVID-19. Skutki epidemii wirusa świńskiej grypy były bardziej bezpośrednio odczuwalne w regionie europejskim. Wiosną 2009 roku pojawił się nowy wirus grypy A (H1N1) (Dandagi & Byahatti, 2011). Początkowo wykryto go w Stanach Zjednoczonych, ale wkrótce rozprzestrzenił się na cały świat. Wirus H1N1 okazał się niebezpieczny dla kobiet w ciąży (Siston et al., 2010). Nieoficjalnie szacuje się, że spowodował śmierć około 200 000 osób (Choi et al., 2019). Epidemia wirusa Ebola w latach 2013–2016 nie dotknęła bezpośrednio mieszkańców Europy (Hasan et al., 2019). Pandemię COVID-19 można było uznać za nową i niepewną sytuację dla całego świata.

Pandemia Covid-19 wymusiła także dyskusję o konieczność i zasadności szczepień kobiet w okresie ciąży. Chociaż początkowo kobietom w ciąży nie oferowano szczepień przeciwko COIVD-19 ze względu na obawy dotyczące ich bezpieczeństwa wytyczne międzynarodowych Centrów Kontroli i Zapobiegania Chorobom Zakaźnym, wskazały zasadność szczepień w okresie ciąży (Skirrow et al., 2022a; *CDC Recommends COVID Vaccine for Pregnant Women | Charles River, n.d.)*. Zalecenia w Wielkiej Brytanii zmieniono już 30 grudnia 2020 r., rekomendując szczepienie kobiet w ciąży, z powodu większego narażenia na zakażenie (kontakt z pracownikami służby zdrowia, personelem pierwszej linii) lub posiadania współistniejących czynników ryzyka (*Joint Committee on Vaccination and Immunisation - GOV.UK*, n.d.). Niedługo potem, kobiety w ciąży zostały włączone do harmonogramów szczepień wraz z resztą populacji, a szczepionki mRNA były preferowanymi produktami do podawania (*Joint Committee on Vaccination and Immunisation - GOV.UK*, n.d.) Według

stanowiska Polskiego Towarzystwa Ginekologów i Położników z kwietnia 2021 roku, szczepionki przeciw COVID-19 powinny być oferowane ciężarnym i kobietom karmiącym. (Stanowisko PTGiP Dotyczące Szczepień Kobiet Ciężarnych Przeciwko COVID19 | Ptgin.Pl, 2021) Skuteczność szczepionki przeciwko COVID-19 u kobiet w ciąży jest porównywalna z osobami niebędącymi w ciąży, a dane dotyczące bezpieczeństwa pochodzą z badań na zwierzętach, a także od kobiet, które nie wiedziały, że są w ciąży w momencie szczepienia (Stock et al., 2022). Ponadto pojawiły się raporty z zakresu nadzoru farmaceutycznego, które nie wykazały żadnych dodatkowych zdarzeń niepożądanych ani powikłań po otrzymaniu szczepionki w ciąży, przy czym dotyczyły one niewielkiej grupy 200 000 zaszczepionych ciężarnych (Fleming-Dutra et al., 2023). Wiadomo, że odsetek szczepień jest znacznie niższy u kobiet w ciąży niż w ogólnej populacji kobiet (Stock et al., 2022). Ciąża jest dobrze znanym czynnikiem powodującym wahania przed szczepieniami, definiowane jako niepewność lub odmowa szczepienia, pomimo dostępności szczepień (Kiefer et al., 2022). Chociaż organizacje medyczne podkreślają potrzebę odpowiedniego poradnictwa i wspólnego podejmowania decyzji przez pracowników służby zdrowia, tylko około połowa kobiet w ciąży w USA jest szczepiona przeciwko grypie i krztuścowi każdego roku (Kiefer et al., 2022). Czynnikami związanymi z wahaniem, są mniejszości etniczne i rasowe, niski status społeczno-ekonomiczny i młody wiek (Kiefer et al., 2022; Skirrow et al., 2022b). Zrozumienie braku akceptowalności szczepionki przeciwko COVID-19 ma kluczowe znaczenie dla obniżenia wskaźników zachorowalności i śmiertelności u kobiet w ciąży, ponieważ 98% kobiet w ciąży przyjętych do szpitala z powodu COVID-19 w jednym z badań nie było zaszczepionych(*Key Information on COVID-19 in Pregnancy | UKOSS | NPEU*, n.d.)

Wybuch pandemii COVID-19 znacząco zmienił warunki diagnostyki i leczenia pacjentek ciężarnych, wpływając nie tylko na ich ogólny stan zdrowia, ale także na aspekty psychologiczne(Nowacka et al., 2021). Ze względu na liczne zmiany układu odpornościowego w czasie ciąży, kobiety ciężarne stają się podatne na patogeny, zwłaszcza wirusy układu oddechowego, co uczyniło je grupą wysokiego ryzyka w czasie pandemii. Zakażenie matki w czasie ciąży zwiększa ryzyko porodu przedwczesnego, ale również innych niekorzystnych skutków(Galang et al., 2020). Chociaż szczepienie przeciwko COVID-19 odgrywa ugruntowaną rolę w zapobieganiu powikłaniom u matki i płodu, wskaźnik wahań wśród kobiet w ciąży pozostaje znaczny. Spośród niezliczonych skutków zakażenia, stwierdzono, że SARS-CoV2 powoduje również bezpośrednie i pośrednie uszkodzenie wątroby, szczególnie u osób z

przewlekłymi chorobami i stanami obniżonej odporności (Li & Xiao, 2020). Choroba COVID-19 jest związana z zajęciem wątroby nie tylko podczas początkowej infekcji, ale także jako jej następstwa (Nardo et al., 2021; Sun et al., 2020). W odniesieniu do ciąży, podwyższony poziom enzymów wątrobowych odnotowano u pacjentek z zakażeniem COVID-19 i wewnątrzwątrobową cholestazą ciążową (ICP) w porównaniu do kobiet niezakażonych COVID-19 (D'Ambrosi et al., 2022). Ponieważ niektórzy autorzy wysunęli hipotezę o możliwej korelacji sekwencji przyczynowo-skutkowej między COVID-19 u matki a ICP (Makhija et al., 2022), celem tego badania była ocena częstości występowania i przebiegu ICP przed i w trakcie pandemii.

Celem niniejszej rozprawy jest zatem analiza, w jaki sposób pandemia COVID-19 wpłynęła na opiekę perinatologiczną, jakie wyzwania i zmiany zostały wprowadzone w odpowiedzi na nowe warunki, oraz jak te zmiany przekształciły zarówno podejście do opieki, jak i oczekiwania pacjentek. Przytaczając wyniki z poszczególnych badań, praca ta dąży do zrozumienia skomplikowanej dynamiki opieki perinatologicznej w czasie globalnego kryzysu zdrowotnego, zwracając uwagę na potencjalne długoterminowe konsekwencje dla zdrowia publicznego.

Cele szczegółowe:

- zbadanie wpływu pandemii COVID-19 na poziom samotności matek, szczególnie w kontekście przymusowego rozdzielenia ciężarnych kobiet od ich partnerów podczas wizyt lekarskich i porodu
- zidentyfikowanie wskaźników przyjmowania szczepień przeciwko COVID-19 wśród kobiet ciężarnych i kobiet po porodzie.
- zbadanie wpływu pandemii COVID-19 na częstość występowania i charakterystykę kliniczną wewnątrzwątrobowej cholestazy ciążowej (ICP).

Hipoteza badawcza:

Postawiono trzy hipotezy badawcze:

1. Pandemia COVID-19 znacząco wpłynęła na opiekę perinatologiczną poprzez wymuszoną separację pacjentek podczas wizyt lekarskich i porodów, ze względu na dostosowanie przez instytucje medyczne swoich procedur i praktyk, dyktowanych pandemią COVID-19.

2. Pandemia COVID-19 znacząco wpłynęła na opiekę perinatologiczną poprzez zmiany w diagnostyce i leczeniu wewnątrzwątrobowej cholestazy ciążowej (ICP).
3. Pandemia COVID-19 znacząco wpłynęła na decyzje ciężarnych kobiet odnośnie do szczepień przeciwko COVID-19.

METODY I WYNIKI

1. Artykuł "*Mother's Loneliness: Involuntary Separation of Pregnant Women in Maternity Care Settings and Its Effects on The Experience of Mothers during the COVID-19 Pandemic"* o wpływie COVID-19 na samotność matek:

- Typ badania: Badanie przekrojowe przeprowadzone w okresie od stycznia do lutego 2021.
- Populacja badana: 1011 kobiet ciężarnych lub tych które urodziły w trakcie pandemii COVID-19.
- Metody zbierania danych: Kwestionariusz samooceny składający się z 44 pytań zamkniętych i otwartych, rozpowszechniany online i w formie papierowej w szpitalu położniczym w Olsztynie. Ankietowane odpowiadały na pytania dotyczące ich zdrowia, statusu społecznego, emocji oraz wpływu funkcjonowania systemu opieki zdrowotnej w czasie pandemii na ich doświadczenia związane z ciążą i porodem.
- Zakres badań: ocena uczuć związanych z samotnością i izolacją, takich jak strach, gniew, poczucie niesprawiedliwości, głęboki smutek i poczucie straty
- Metody analizy statystycznej: W tym przypadku zastosowano statystykę opisową, aby uzyskać ogólny obraz odpowiedzi na pytania ankietowe. Analiza regresji wielorakiej została użyta do zrozumienia, jak różne zmienne takie jak wiek, status zawodowy czy wykształcenie wpływają na poziom doświadczanej samotności i innych emocji. Te analizy pozwoliły na zrozumienie głębszych korelacji i potencjalnych przyczyn występujących zjawisk.

2. Artykuł *"COVID-19 Vaccination Status among Pregnant and Postpartum Women—A Cross-Sectional Study on More Than 1000 Individuals"* o stanie szczepień przeciwko COVID-19 wśród kobiet ciężarnych i po porodzie:

- Typ badania: Prospektywne badanie przekrojowe przeprowadzone w ośrodku medycyny matczyno-płodowej.
- Populacja badawcza: 1033 kobiety ciężarne i po porodzie.
- Metody zbierania danych: Ankieta oceniająca czynniki socjodemograficzne i percepcje dotyczące szczepień przeciwko COVID-19, grypie i krztuścowi. Uczestniczki rekrutowano osobiście oraz telefonicznie, a ankiety rozprowadzano zarówno w formie papierowej, jak i online.

- Zakres badań: Ankieta oceniała czynniki socjodemograficzne oraz percepcje dotyczące szczepień przeciwko COVID-19, grypie i krztuścowi. Pytania dotyczyły przyjowania szczepień, opinii na temat szczepień w ciąży, wcześniejszych doświadczeń związanych z ekspozycją oraz kluczowych czynników w procesie decyzyjnym.
- Metody analizy statystycznej: Do analizy danych ankietowych użyto regresji logistycznej, aby zbadać związki między cechami demograficznymi a postawami wobec szczepień przeciwko COVID-19, grypie i krztuścowi. Regresja pozwoliła zidentyfikować predyktory, które istotnie wpływają na decyzję o szczepieniu, takie jak poziom wykształcenia, zaufanie do informacji medycznych oraz wcześniejsze doświadczenia ze szczepieniami.

3. Artykuł *„Intrahepatic Cholestasis of Pregnancy during COVID-19 Pandemic”* o wewnątrzwątrobowej cholestazie ciążowej (ICP) w czasie pandemii COVID-19:

- Typ badania: Retrospektywne badanie kohortowe przeprowadzone w dwóch ośrodkach.
- Populacja badawcza: Kobiety ciężarne z diagnozą ICP zdefiniowaną jako poziomy kwasów żółciowych $\geq$ 10 μmol/L bez wcześniejszych chorób wątroby, w ciążach pojedynczych i bliźniaczych.
- Metody zbierania danych: Dane pozyskano z systemów danych szpitalnych, analizowano m.in. mnogość ciaży, zakażenie COVID-19, maksymalne poziomy enzymów wątrobowych i kwasów żółciowych, a także dane dotyczące porodu.
- Zakres badań: Porównanie danych klinicznych, takich jak objawy, wyniki badań laboratoryjnych i skuteczność zastosowanych terapii.
- Metody analizy statystycznej: Użyto statystyki opisowej, analizy regresji logistycznej i wielorakiej. Skorzystano z testów Chi-kwadrat do porównywania częstości występowania ICP przed i w trakcie pandemii. Dodatkowo, użyto testu U Manna-Whitneya do porównywania ciągłych zmiennych, takich jak poziomy enzymów wątrobowych, między grupami. W celu zidentyfikowania czynników ryzyka zastosowano analizę regresji logistycznej, biorąc pod uwagę takie zmienne jak wiek pacjentek, rodność, a także historię infekcji COVID-19.

Wykorzystane w niniejszej pracy metody badawcze zapewniły solidne podstawy do zgłębienia różnorodnych aspektów zdrowia i dobrostanu kobiet w okresie ciąży i połogu w kontekście pandemii COVID-19 oraz wpływu na decyzje dotyczące szczepień.

Oto wyniki zaprezentowane w trzech artykułach:

1. Artykuł z "International Journal of Environmental Research and Public Health" o samotności ciężarnych podczas pandemii:

Badanie potwierdziło główną hipotezę, że kobiety w ciąży doświadczały podwyższonego poziomu samotności związanego z pandemią i związanymi z nią środkami sanitarnymi, co miało znaczący wpływ na ich jakość życia. Aż 84,37% ankietowanych kobiet przyznało, że podczas ciąży nie mogły uczestniczyć w wizytach lekarskich ze swoimi partnerami, a 66,27% rodziło samotnie z powodu zakazów związanych z pandemią.

2. Artykuł z "Vaccines" o stanie szczepień przeciwko COVID-19 wśród kobiet ciężarnych i po porodzie:

Z badania wynika, że 54,1% ankietowanych kobiet było w ciąży, a 45,9% w połogu podczas wypełniania ankiety. Podział respondentek na zaszczepione przed ciążą, w trakcie ciąży oraz planujące szczepienie pokazał, że większość uczestniczek (59,3%) zdecydowała się na szczepienie.

3. Artykuł z "Medicina" o wewnątrzwątrobowej cholestazie ciążowej (ICP) podczas pandemii COVID-19:

Badanie wykazało niższą częstość występowania ICP w trakcie pandemii w porównaniu do okresu przed pandemią (3,6% wobec 2,4%, $p = 0,01$). Mimo że częstość łagodnej ICP (BA < 40 μmol/L) była niższa w trakcie pandemii, występowanie umiarkowanej i ciężkiej ICP (BA ≥ 40 μmol/L) pozostało stabilne.

Te wyniki pokazują różnorodny wpływ pandemii COVID-19 na zdrowie i dobrostan kobiet w okresie perinatalnym, od fizycznych aspektów zdrowia po emocjonalne i psychologiczne doświadczenia związane z ciążą i porodem.

PODSUMOWANIE I WNIOSKI

1. Wykazano znaczące negatywne skutki psychologiczne separacji ciężarnych od partnerów w placówkach opieki zdrowotnej w trakcie pandemii COVID-19. Analiza danych ujawniła znaczący wzrost poziomu lęku i stresu wśród respondentek, co podkreśla krytyczną potrzebę przemyślanej modyfikacji procedur medycznych oraz wsparcia psychologicznego dla ciężarnych i matek w okresie globalnego kryzysu zdrowotnego.
2. Wykazano, że wyższe wykształcenie oraz pozytywne interakcje z pracownikami ochrony zdrowia zwiększały prawdopodobieństwo zgody na szczepienie przeciw COVID-19 ciężarnych pacjentek, natomiast głównym powodem odmowy były obawy dotyczące bezpieczeństwa szczepionek. Te wyniki wskazują na znaczenie edukacji zdrowotnej i komunikacji w promowaniu zdrowia publicznego
3. Wykazano spadek liczby łagodnych przypadków wewnątrzwątrobowej cholestazy ciążowej (ICP), co może świadczyć o barierach w dostępie do opieki medycznej oraz zmianach w procedurach diagnostycznych podczas pandemii. Stabilność częstości ciężkich przypadków ICP wskazuje na konieczność utrzymania wysokiego poziomu czujności klinicznej w zarządzaniu przypadkami zagrożenia zdrowotnego dla matki i dziecka, podczas przyszłych pandemii.

Wszystkie trzy artykuły opisują sytuację pacjentek ciężarnych podczas pandemii COVID-19. Zwracając uwagę na wpływ pandemii na opiekę zdrowotną oraz konieczność holistycznego podejścia do opieki perinatologicznej w czasie pandemii. Podkreślają znacznie elastyczności systemów opieki zdrowotnej, które powinny być przygotowane nie tylko na fizyczne aspekty opieki, ale także wsparcie emocjonalne i psychiczne pacjentek. Istotnym wydaje się opracowanie długoterminowych strategii, mogących zminimalizować negatywne skutki podobnych wydarzeń w przyszłości. Jednocześnie kładąc nacisk na potrzebę dalszych badań nad wpływem pandemii na diagnozowanie i leczenie pacjentek w ciąży, a także znaczenie zapewnienia ciągłości opieki zdrowotnej dla ciężarnych

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Mother's Loneliness: Involuntary Separation of Pregnant Women in Maternity Care Settings and Its Effects on the Experience of Mothers during the COVID-19 Pandemic

Paulina Malarkiewicz [1,*], Stanisław Maksymowicz [2] and Maria Libura [3]

[1] Department of Obstetrics and Gynaecology, School of Medicine, Collegium Medicum of the University of Warmia and Mazury, al. Warszawska 30, 10-082 Olsztyn, Poland
[2] Department of Psychology and Sociology of Health and Public Health, School of Public Health, Collegium Medicum of the University of Warmia and Mazury, al. Warszawska 30, 10-082 Olsztyn, Poland; stanislaw.maksymowicz@uwm.edu.pl
[3] Medical Education and Simulation Department, School of Medicine, Collegium Medicum of the University of Warmia and Mazury, al. Warszawska 30, 10-082 Olsztyn, Poland; maria.libura@uwm.edu.pl
* Correspondence: paulina.malarkiewicz@uwm.edu.pl

Abstract: The aim of the study was to investigate the challenges of involuntary separation experienced by women during pregnancy and childbirth in the time of the COVID-19 pandemic. The study was conducted by the means of a self-administered questionnaire. One thousand and eleven women (1011) from Poland took part in the study, with an average age of approximately 30 years. The study was approved by the Research Ethics Committee of Warmia and Mazury University in Olsztyn, Poland. The results show that the majority of the surveyed women experienced involuntary separation from their partners during pregnancy and childbirth: 66.27% had no choice but to give birth alone and 84.37% had not been able to attend medical appointments with their partners. Solitary encounters with healthcare were associated with the feeling of fear (36.4%), anger (41%), a sense of injustice (52.2%), acute sadness (36.6%) and a sense of loss (42.6%), with all the reported levels higher in younger women. Over 74% of respondents were afraid of childbirth without a partner present. Almost 70% felt depressed because of a lonely delivery experience. Nearly a quarter of the mothers surveyed declared that if they could go back in time, they would not have made the decision to become pregnant during the pandemic. Based on our study, we found that adjustments to prenatal and neonatal care arrangements under COVID-19-related regimens are needed. Our proposal is to implement at least three fundamental actions: (1) risk calculations for pandemic-related cautionary measures should take into account the benefits of the accompanied medical appointments and births, which should be restored and maintained if plausible; (2) medical personnel should be pre-trained to recognise and respond to the needs of patients as a part of crisis preparedness. If the situation does not allow the patient to stay with her family during important moments of maternity care, other forms of contact, including new technologies, should be used; (3) psychological consultation should be available to all patients and their partners. These solutions should be included in the care plan for pregnant women, taking into account a risk-benefit assessment.

Keywords: pregnancy; separation; anxiety; COVID-19; quality of life; maternity care

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1. Introduction

Pregnancy is a time of radical changes in the lives of expecting mothers, involving biological, physiological and social functioning spheres. This time is also marked by evolving relationships, especially those with the closest partner/father of the child, beginning with the predominantly mutually agreed decision to become pregnant, throughout the duration of pregnancy itself, to childbirth and postpartum experience. At each of these stages, stress, anxiety and other mental health challenges or even psychiatric disorders may appear. Thus,

preparing for the role of a mother and undergoing pregnancy-associated transitions is a possible trigger of psychological disorders, such as antenatal anxiety and depression [1,2]. Often, fears for the success of the pregnancy, the proper development of the fetus and the course of delivery, are also present. One can experience a wide range of emotions during pregnancy, which may often be quite extreme [3].

Mental health disorders become particularly challenging when life and/or health threatening situations occur on a wider social plane, which is undoubtedly the case with the COVID-19 (coronavirus) pandemic that started worldwide in 2020 [4]. Currently, women of a reproductive age do not remember the earlier pandemics of the twentieth centuries, while the more recent ones had a limited impact in terms of social reception in most countries. The global pandemic of severe acute respiratory syndrome (SARS) in 2002–2003 was the first in the 21st century [4]. Yet, since it contained only residents of the threatened areas who were faced with accompanying mental health challenges, the rest of the world were mostly observers. Additionally, the SARS pandemic did not cause as much fear and did not record as many deaths as the COVID-19 pandemic. The swine flu virus epidemic effects were more directly felt in the European region. In the spring of 2009, a new influenza A virus (H1N1) emerged [5]. At first, it was detected in the United States, but soon it spread across the world. H1N1 turned out to be dangerous for pregnant women [6]. It is unofficially estimated that it caused the deaths of approximately 200,000 people [7]. The Ebola epidemic in 2013–2016 did not directly affect European residents [8].

The COVID-19 pandemic can be considered a new and uncertain situation for most of society. No government or healthcare system was prepared for such a crisis. Undoubtedly, the threat to life and/or health associated with a novel infectious disease is a major stress factor. The measures aimed at mitigating the risk of infection themselves may also pose an additional burden on patients. The pandemic also significantly impacted the functioning of the healthcare system, maternity care included. At the beginning of the pandemic in 2020, health officials in Poland suggested that it was advisable to postpone any plans of family enlargement because of potential negative effects of COVID-19 on pregnancy, as well as the limitations in the functioning of hospitals and gynecology clinics. PTGiP (Polish Society of Obstetricians and Gynecologists), following the international guidelines [9], recommended to suspend family births on 20 March 2020. The possibility of accompanying the partner during the ultrasound examination of the pregnant woman was also suspended [10]. However, some pregnancies were already underway, not to mention the fact that it is impossible to suspend reproduction in the entire population. Therefore, the prenatal care had to function in reality of shifting guidelines and changing pandemic restrictions.

The aim of our study was to analyze how the COVID-19 pandemic influenced the quality of life of pregnant women, how it affected their, and their partners, well-being and whether it translates into their future procreative plans.

The pivotal theme of the study is loneliness, resulting from lonely doctor visits and childbirth. Cacioppo et al. defines loneliness as "subjective distress resulting from a discrepancy between desired and perceived social relationships" [11]. Jeste et al. in JAMA Psychiatry suggests that loneliness is a modern epidemic, resulting in serious health disorders [12].

In our study, loneliness turned out to be the dominant emotion during the initial conversations with both pregnant women and women who gave birth to a child under sanitary restrictions, which one of the authors of this study conducted in her medical practice. Medical interviews, which practically piloted the main study, were filled with patients' complaints about exactly this issue, showing how important this problem was to women and that it requires systematic scientific investigation.

We also wanted to present recommendations aimed at improved focus on mental well-being in maternity care for possible subsequent waves of COVID-19 or future pandemics. The main hypothesis of the present study is the following: pregnant women experienced elevated levels of loneliness linked to the coronavirus pandemic and related sanitary

measures, which had a significant impact on their quality of life [13] and procreative plans (planned family expansion).

2. Materials and Methods

The study, approved by the Research Ethics Committee of Warmia and Mazury University in Olsztyn, Poland (No. 6/2021), was carried out from January to February 2021, during the second wave of the coronavirus pandemic in Poland. The conditions for participation in the study were: adult age, ongoing pregnancy or delivery during the COVID-19 pandemic and informed consent to participate in the study.

The study was conducted using a self-report questionnaire (on-line and paper), consisting of 44 questions: 42 closed, single-choice and single-choice Likert scale questions and 2 open-questions, divided into 5 domains: (1) demographic data (6 questions), (2) patient's health status (9 questions), (3) patient's social standing during pregnancy and childbirth (6 questions), (4) patient's emotions (17 questions) and (5) the impact of the health care system functioning during a pandemic on the patient's experiences of pregnancy and childbirth (6 questions).

The questionnaires were disseminated via the Internet and at one maternity hospital in Olsztyn, Poland. The online survey tool was created using a commonly utilized platform, https://docs.google.com/ (accessed on 19 April 2022), which allows respondents to anonymously complete a survey on both mobile devices and standard computers. Investigators used the snowball sampling method to deliver the survey invitation letter with the survey URL to potential participants via the Instagram account, Facebook and email. Participants were invited to forward the survey invitation letter with the survey link to their friends and relatives. All individuals were freely participating in the study and had the option to discontinue at any moment. The survey was anonymous and confidential, and it took about 10 min to complete.

One thousand and eleven women (1011) took part in the study, aged from 17 to 50. A total of 899 participants filled the online form, while one hundred twelve (112) completed the pen and paper version. The average age was 29.5 years. The participants had a higher education degree equivalent to the Master's level (59.1%, n = 597), secondary education (21.8%, n = 235) or a Bachelor's degree (16.5%, n = 166). A total of 82.3% (n = 832) of the respondents indicated that they were currently employed, 14.8% (n = 150) were unemployed and 2.9% (n = 29) were studying. The distribution of the place of residence variable was relatively equal, with a slight predominance of villages and large cities. Most of the respondents remained in a permanent formal relationship (77.7%, n = 786), with 20.7% (n = 209) declaring an informal relationship status.

A total of 49.9% (n = 504) of respondents gave birth during the pandemic, before participating in the survey. The remaining women (50.1%, n = 507) were pregnant during the pandemic (they were awaiting delivery at the time of filling in the questionnaire). The structure of the study group is presented in Table 1.

Table 1. Characteristics of the studied group.

		Count	Column N % (N = 1011)
Age	17–24	110	10.9%
	25–29	423	41.8%
	30–34	347	34.3%
	35–39	114	11.3%
	40–44	15	1.5%
	45–50	2	0.2%

Table 1. *Cont.*

		Count	Column N % (N = 1011)
Education	Primary education	13	1.3%
	Secondary education	235	23.2%
	Higher education—Bachelor's degree	166	16.4%
	Higher education—Master's degree	597	59.1%
Occupational status	Employed	832	82.3%
	Studying	29	2.9%
	Unemployed	150	14.8%
Place of residence (the number of residents)	Countryside	237	23.4%
	City up to 50,000	208	20.6%
	City 50,000–150,000	131	13.0%
	City 150,000–500,000	196	19.4%
	City over 500,000	239	23.6%
Marital status	Single	10	1.0%
	In an informal relationship	209	20.7%
	Married	786	77.7%
	Divorced	4	0.4%
	Widowed	2	0.2%
Health status (pregnancy and childbirth)	Pregnant during the pandemic (responded before giving birth)	507	50.1%
	Gave birth during the pandemic	504	49.9%
Involuntary separation	Solo medical appointments during pregnancy (among all studied women)	853	84.37%
	Solo childbirth (among women who gave birth)	334	66.27%

Statistical Analysis and Variable Measurement

Microsoft Excel and IBM SPSS Statistics 27 (Armonk, NY, USA: IBM Corp) were used to perform the analysis. To present the overall characteristics of the data, descriptive statistics for all study variables were calculated. Then, the Pearson's correlation coefficients and multivariate linear regression analysis were calculated to determine covariates. A two-tailed significance level of 0.05 was used in all statistical tests. The odds ratio was calculated with MedCalc (https://www.medcalc.org/calc/odds_ratio.php (accessed on 5 April 2022).

The internal consistency of the scales was computed using Cronbach's alpha coefficient. The internal consistency of the items in this study are the following: for the Likert scale questions about emotions related to separation, Cronbach's alpha is 0.904 (excellent); for the Likert scale questions about women's emotions, Cronbach's alpha is 0.804 for pregnant women (acceptable); while for those who gave birth, Cronbach's alpha is 0.764 (acceptable) [14].

The problem of involuntary separation was measured through independent variables: medical visits and delivery status (single or not). The effect of the involuntary separation on quality of life and well-being was measured through dependent variables: (1) increased anxiety, anger, a sense of injustice, acute sadness, a sense of loss (one scale); reduced joy of pregnancy; (2) fear of giving birth alone, low mood regarding the vision of a solo childbirth, fear of lonely hospitalization, fear of isolation from the baby and concern for the health of the baby (one scale—pregnant); (3) influence of solo childbirth on the joy of pregnancy, anxiety during a solo childbirth, fear of lonely hospitalization, fear of isolation from the baby and concern for the health of the baby (one scale—gave birth) (see Figure 1).

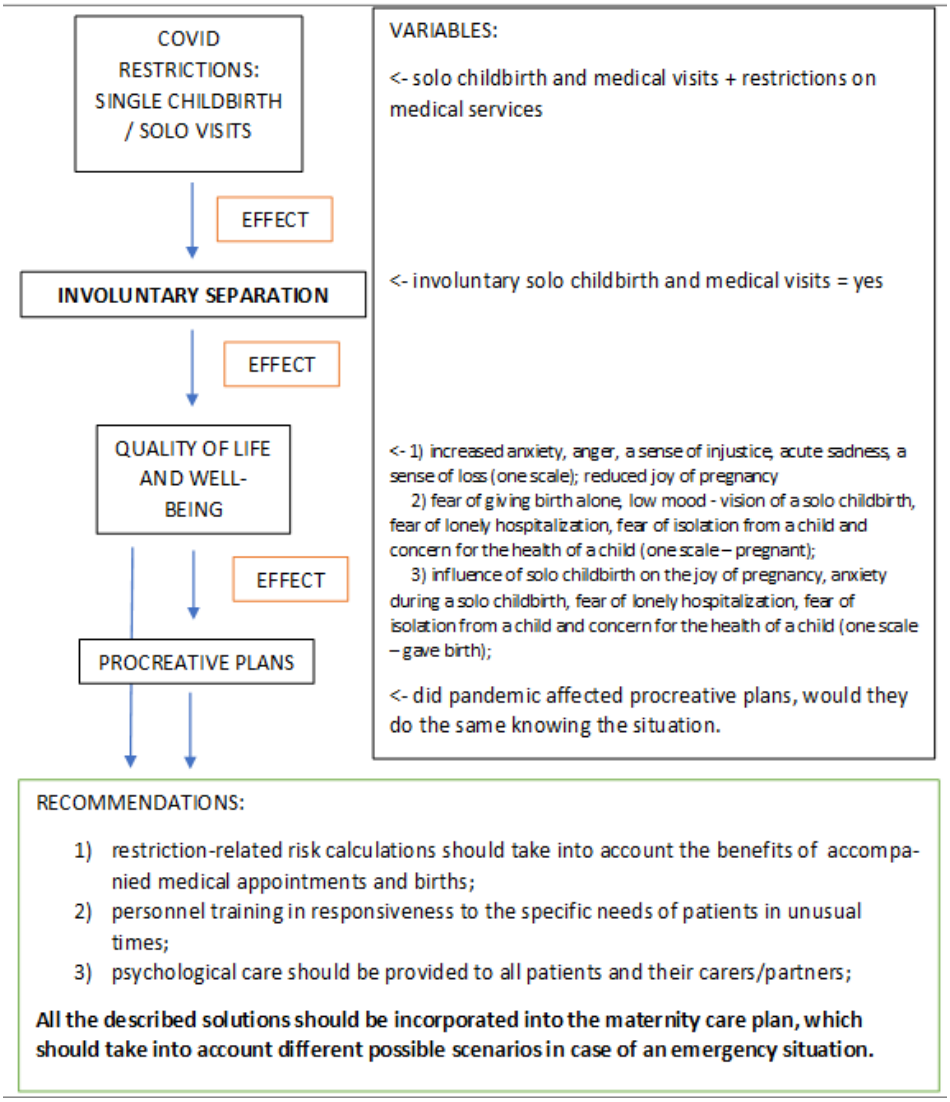


Figure 1. Involuntary separation-measured variables, income and outcome.

3. Results

3.1. Separation and Emotions

The main hypothesis of the present study is that pregnant women would experience elevated levels of loneliness linked to the coronavirus pandemic and related sanitary measures, which would have a significant impact on their quality of life, was confirmed. The most important limitation for pregnant women was the inability of the partner to participate in prenatal care appointments and be present during delivery. We called this phenomenon, involuntary separation. This term means that the separation of the patient from her closest social circle is imposed rather than chosen. The way in which the problem was measured and its impact on the quality of life, well-being, procreative plans as well as the resulting recommendations, are shown in Figure 1.

Among all the women surveyed, 84.37% (n = 853) admitted that during pregnancy, they had not been able to attend medical appointments with their partners. Respondents who gave birth during the pandemic, in 66.27% (n = 334) of cases, had to do it alone due to pandemic-related measures. Only for 7.34% (n = 37), it was a chosen option. Furthermore, 26.39% (n = 133) were allowed to have a husband/partner by their side at the time of delivery. As a result of multiple regression analysis with Age, Education, Occupational status, Place of residence size and Marital status as independent variables and Partner's

participation in medical appointments as a dependent variable, one can conclude that there were no significant differences in any of the variables.

Respondents indicated that due to lonely doctor appointments, they experienced increased anxiety (36.4%, n = 368), anger (41%, n = 415), a sense of injustice (52.2%, n = 527), acute sadness (36.6%, n = 369) and a sense of loss (42.6%, n = 431). This problem affected both groups of respondents (pregnant women and those who had already given birth at the time of questionnaire completion) equally, as both were limited by the systemic restrictions.

The impact of separation shown as a series of negative emotions proved to be strongly associated with some demographic variables. The age of the patient was significantly negatively associated with all negative experiences. This means that the younger the women, the higher the index of negative emotions accompanying the separation. Another age-related variable was the level of education, which again was strongly associated with the experience of anger, a sense of injustice and overwhelming sadness. Marital status was not as strongly associated with the emotions of anger and an overwhelming sadness. The other measured demographic variables, such as occupational status and place of residence size, were not statistically significantly associated with negative emotions (Table 2A).

Table 2. (**A**) Pearson correlation between demographic variables and perceived emotions related to separation. (**B**) Multivariate linear regression analysis and odds ratio.

(A)						
		Age	**Education**	**Occupational Status**	**Place of Residence Size**	**Marital Status**
Increased anxiety	Pearson correlation Sig. (two-tailed) N	−0.125 ** <0.000 822	−0.061 0.081 822	−0.002 0.963 822	0.048 0.168 822	−0.047 0.174 822
Anger	Pearson correlation Sig. (two-tailed) N	−0.202 ** <0.000 829	−0.149 ** <0.000 829	0.013 0.719 829	−0.043 0.211 829	−0.075 * 0.031 829
Feeling of injustice	Pearson correlation Sig. (two-tailed) N	−0.181 ** <0.000 832	−0.098 ** <0.005 832	0.006 0.854 832	−0.027 0.439 832	−0.049 0.155 832
Overwhelming sadness	Pearson correlation Sig. (two-tailed) N	−0.177 ** <0.000 823	−0.138 ** <0.000 823	0.034 0.335 823	−0.026 0.465 823	−0.087 * 0.013 823
A sense of loss	Pearson correlation Sig. (two-tailed) N	−0.111 ** <0.001 826	−0.056 0.106 826	−0.034 0.326 826	0.056 0.107 826	−0.039 0.258 826
(B)						
		Age	**Education**	**Occupational Status**	**Place of Residence Size**	**Marital Status**
Increased anxiety	Standardized Coefficients Beta Sig.	−0.126 <0.001	−0.038 0.334	−0.028 0.445	0.070 0.051	−0.019 0.591
	OR (CI and p-value)	1.54 (1.17 to 2.04, p = 0.0021)	1.33 (0.97 to 1.84, p = 0.0781)	0.92 (0.64 to 1.32, p = 0.6646)	0.8 (0.60 to 1.06, p = 0.1204)	1.44 (1.03 to 2.03, p = 0.0327)
Anger	Standardized Coefficients Beta Sig.	−0.176 <0.001	−0.102 0.008	−0.058 0.108	−0.002 0.958	−0.026 0.459
	OR (CI and p-value)	1.80 (1.36 to 2.37, p < 0.0001)	1.77 (1.28 to 2.45, p = 0.0005)	0.83 (0.58 to 1.19, p = 0.3200)	1.14 (0.86 to 1.50, p = 0.3458)	1.5 (1.07 to 2.12, p = 0.0172)
Feeling of injustice	Standardized Coefficients Beta Sig.	−0.171 <0.001	−0.052 0.172	−0.045 0.215	0.002 0.950	−0.012 0.734
	OR (CI and p-value)	1.62 (1.22 to 2.15, p = 0.0009)	1.43 (1.02 to 1.02, p = 0.0386)	0.97 (0.66 to 1.41, p = 0.8808)	1.07 (0.8 to 1.42, p = 0.6278)	1.46 (1.01 to 2.10, p = 0.0402)
Overwhelming sadness	Standardized Coefficients Beta Sig.	−0.147 <0.001	−0.090 0.020	−0.027 0.467	0.013 0.722	−0.044 0.216
	OR (CI and p-value)	1.82 (1.38 to 2.4, p < 0.0001)	1.63 (1.18 to 2.24, p = 0.0029)	0.83 (0.057 to 1.19, p = 0.3229)	1.12 (0.85 to 1.48, p = 0.4095)	1.42 (1.0 to 1.98, p = 0.0438)
A sense of loss	Standardized Coefficients Beta Sig. OR (CI and p-value)	−0.116 0.002 1.18 (0.9 to 1.55, p = 0.023)	−0.048 0.218 1.16 (0.84 to 1.6, p = 0.3538)	−0.059 0.108 1.16 (0.81 to 1.68, p = 0.3975)	0.074 0.040 0.76 (0.58 to 1.01, p = 0.0617)	−0.013 0.723 1.22 (0.87 to 1.71, p = 0.2446)

** Correlation is significant at the 0.01 level (two-tailed). * Correlation is significant at the 0.05 level (two-tailed).

The multivariate linear regression analysis of independent variables (demographic: Age, Education, Occupational status, Place of residence and Marital status) and dependent variables (Increased anxiety, Anger, Feeling of injustice, Overwhelming sadness and a Sense of loss) confirmed that there is a strong association between dependent variables and a younger age (Beta for Increased anxiety is −0.126, for Anger is −0.176, for Feeling of injustice is −0.171, for Overwhelming sadness is −0.147 and for a Sense of loss is −0.166; all variables are significantly associated). Anger was also significantly associated with Education (Beta is −0.102). Multivariate linear regression analysis and odds ratio are shown in Table 2B. The detailed results of the regression analysis are in the Supplement file: Table S1–S5.

The odds ratio for independent variable, Age, and Increased anxiety is 1.54 (1.7 to 2.04, $p = 0.0021$), Anger is 1.8 (1.4 to 2.4, $p < 0.0001$), Feeling of injustice is 1.6 (1.2 to 2.2, $p = 0.0009$), Overwhelming sadness is 1.8 (1.4 to 2.4, $p < 0.0001$) and a Sense of loss is 1.18 (0.9 to 1.5, $p = 0.023$, insignificant). The odds ratio was also significant for Education and Anger, and is 1.77 (1.28 to 2.45, $p = 0.0005$). Thus, it was confirmed that the problems related to separation concern young women to a greater extent. Other variables are not significantly associated (Table 2B).

For the further part of the analysis, our sample was divided into two groups: (1) women who were pregnant during the pandemic (at the time they completed the questionnaire) and (2) women who gave birth during the pandemic (before they completed the questionnaire).

Our assumption was that the experiences of these groups, although similar, will differ on selected planes. Both groups indicated that the loneliness they experienced in maternity care affected their overall well-being, and might also have far-reaching effects.

3.1.1. Women Who Were Pregnant during the Pandemic

The majority of women in this group admitted that they were afraid of a lonely childbirth (74.1%, $n = 376$, of which 55.4%, $n = 281$ were definitely afraid of such a situation). For 69.6% ($n = 353$), this perspective was a cause of a lowered mood, and this applied to all women regardless of demographic characteristics or other tested variables.

Even more pregnant women were afraid of a lonely hospital stay (76.6%, $n = 388$). This worry was statistically significantly (Pearson correlation) associated with a younger age ($p < 0.002$), but also with the lower level of education ($p < 0.023$) and occupational status ($p < 0.047$). A total of 84.8% ($n = 430$) of women in this group were also concerned with the prospect of isolation from their child after childbirth (without significant demographic differences). Slightly less, 78.7% ($n = 399$), were anxious about their child's health (variable significantly related to marital status, $p < 0.022$). The above data are illustrated in Figure 2.

3.1.2. Women Who Gave Birth during the Pandemic

Such fears of pregnant woman were mirrored by the experiences of those who gave birth during the pandemic. First of all, a large proportion of respondents in this group (62.9%, $n = 317$) declared that the absence of a partner during childbirth negatively impacted their level of happiness. This reduction was statistically significantly (Pearson correlation) associated with occupational status ($p < 0.008$), the course of childbirth (i.e., giving birth alone, $p < 0.015$) and partner's participation in earlier medical appointments (associating with lonely medical appointments, $p < 0.016$).

A higher level of anxiety (reported by 68.7% of participants, $n = 346$) was statistically significantly (Pearson correlation) associated with a lower age ($p < 0.002$) and a lack of partner's participation in medical appointments ($p < 0.030$). Women giving birth during the pandemic also admitted that they were afraid of loneliness during hospitalization, resulting from visiting policies (64.5%, $n = 325$); this variable was significantly associated with a lower age ($p < 0.002$). Many women experienced the fear of being separated from their child (80%, $n = 403$), another variable significantly associated with a lower age at the p level of <0.011 (even though only about 5% were actually separated from the child), as well as fears concerning their infant's health (77.5%, $n = 391$, without any statistically significant

association with demographic and other variables). The above data are illustrated in Figure 3.

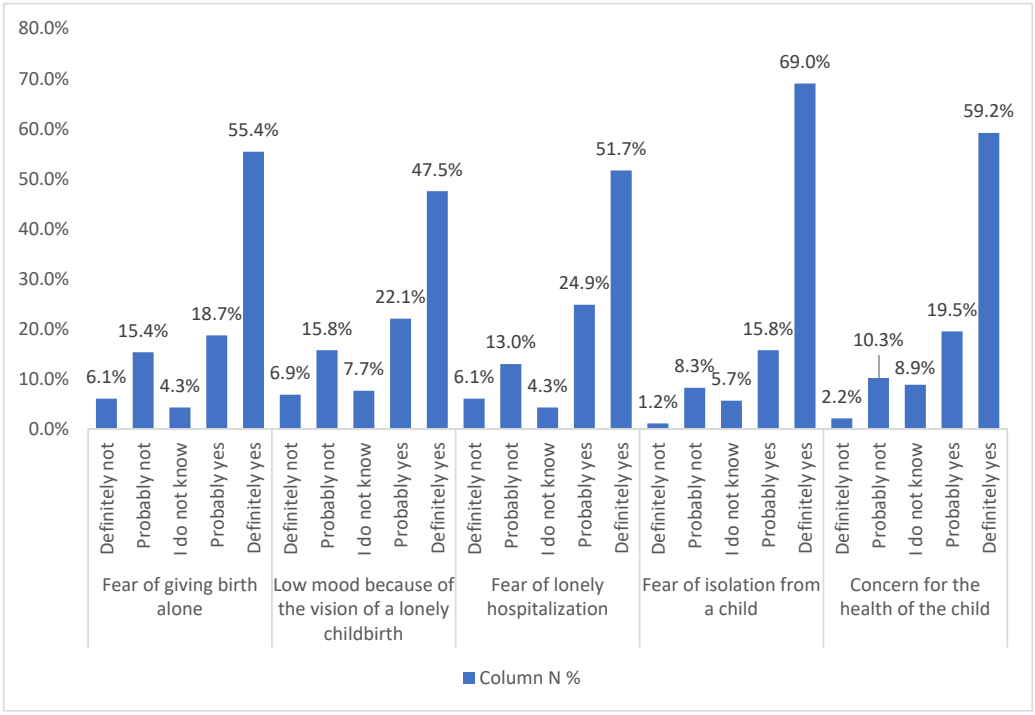


Figure 2. Emotions related with pregnancy (n = 507).

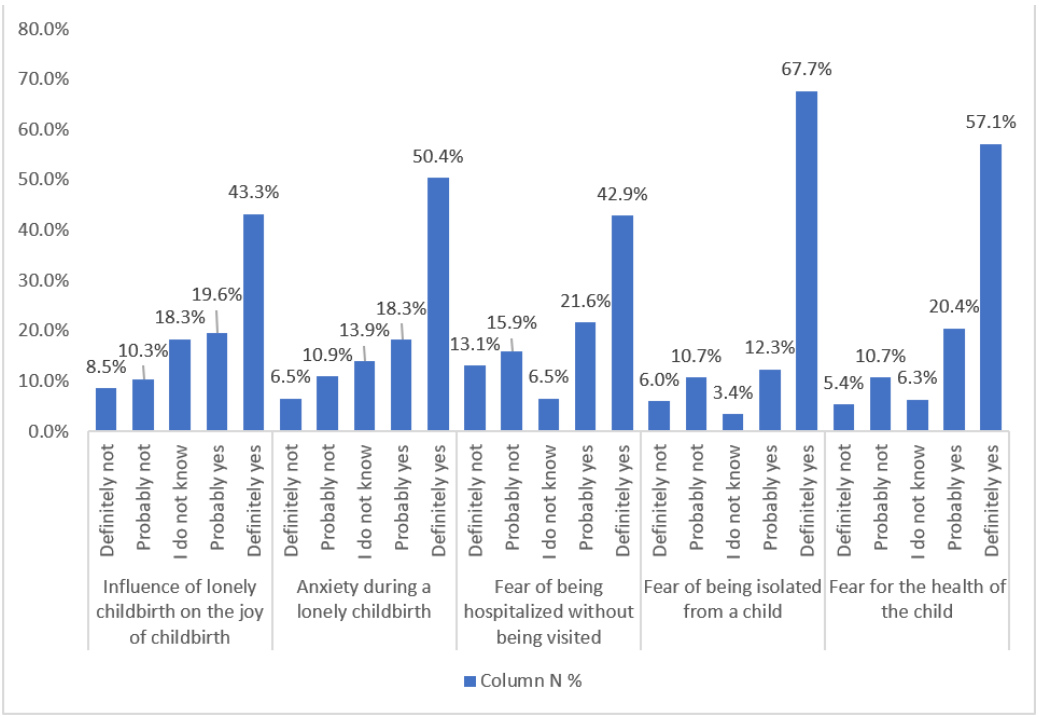


Figure 3. Emotions related with childbirth (n = 504).

3.2. Restrictions and Healthcare System

We also examined how the pandemic restrictions influenced the experiences related to pregnancy in general, and the encounters with the healthcare system's services in particular. Almost a third of the women surveyed admitted that the pandemic restrictions reduced

their happiness during pregnancy (29%, n = 293 of the respondents indicated "definitely yes" or "probably yes"; 50.5%, n = 511 indicated "probably not" and "definitely not"; 20.5%, n = 207 do "not know"; a statistically significant association with demographic variables was found only with the place of residence variable ($p < 0.005$, Pearson correlation), and it was stronger in smaller towns and villages).

One of the limitations mentioned in the questionnaire was related to the availability of maternity care services, especially the restricted access to medical examinations. A total of 18% (n = 182) of the respondents indicated that due to the pandemic, they missed some prenatal care appointments, between two or three on average. Due to the restrictions, 17% (n = 172) experienced a limited access to health services, including tests and vaccinations. Among the most frequently indicated were: vaccinations, OGTT 75 g (Oral Glucose Tolerance Test), 11 to 13 + 6 scan (first trimester screening), second trimester anomaly scan and amniocentesis.

In extreme cases, as some women wrote in the survey, no tests were performed other than one ultrasound. Access to basic tests such as blood count and urinalysis was also difficult. One of the respondents wrote in a comment that some of the appointments took the form of teleconsultations (one may suspect that these were relatively frequent, but we did not ask the respondents directly).

Respondents were asked if their pregnancy care was altered by the pandemic: 18% (n = 182) indicated that the care quality worsened, 49.2% (n = 497) declared it did not change, while for 1.6% (n = 16), it improved, with 31.3% (n = 316) expressing no opinion. Thus, taking into account both restricted access and perceived care quality, nearly 1/5 of respondents experienced lower care quality and/or accessibility due to the pandemic, regardless of demographic characteristics.

As many as a quarter of the respondents (23.9%, n = 242) declared that they would have waited until the end of the pandemic before getting pregnant if they had known what was awaiting them. However, when asked whether the pandemic influenced their decision to get pregnant, the majority of women (78.3%, n = 792) admitted that it did not influence their decision (Table 3).

Table 3. Effects of epidemic restrictions.

		Count	Column N % (N = 1011)
Impact of pandemic restrictions on happiness during pregnancy: reduced happiness	Definitely and probably yes	293	29%
	Definitely and probably not	511	50.5%
	Do not know	207	20.5%
Healthcare availability during pandemic (% does not accumulate—affirmative answers from different questions)	Missed prenatal care appointments	182	18%
	Limited access to health services	172	17%
	Limited access to main doctor	170	16.8%
	Limited access to the hospital emergency ward	275	27.2%
Healthcare quality during pandemic	Worsened	182	18%
	Did not changed	497	49.2%
	Improved	16	1.6%
	Hard to say	316	31.3%
Access to information related to childbirth since the onset of pandemic	Did not received all sufficient information	408	40.4%
	Received, but lacked sufficient information	251	24.8%
	Received all sufficient information	352	34.8%

Table 3. *Cont.*

		Count	Column N % (N = 1011)
Relations with healthcare personnel	Worsened	214	21.2%
	Did not changed	709	70.1%
	Improved	88	8.7%
Decision to get pregnant	I would do the same	769	76.1%
	I would not decide to get pregnant	242	23.9%
Did the pandemic influence the decision to get pregnant?	No	792	78.3%
	Yes	85	8.4%
	Hard to say	134	13.3%

Moreover, participants in our study suffered from restricted access to information related to childbirth since the onset of pandemic. A total of 40.4% (n = 408) of the women said that they did not receive any information. A total of 24.8% (n = 251) said that the information they received was insufficient. Relations with healthcare personnel were also affected, with more than 1/5 of the respondents (21.2%, n = 214) declaring deterioration in this respect. Detailed results of the measurement of the effect of epidemic restrictions are presented in Table 3.

4. Discussion

Pregnancy involves a complex psychological process [15]. The fertility of a woman, her age, socioeconomic status and family situation are important factors [16]. The course of pregnancy involving complications also increases the incidence of depression in pregnant women. The context of the pandemic had a significant impact on the mental well-being of our respondents, which is in line with other research; in the systematic review of the prevalence of anxiety during the COVID-19 pandemic, it proved to be significantly higher among females, especially in Europe [17].

Anxiety is the most common mental health issue present during pregnancy. Rauf et al. found that during the pandemic, women experienced increased perinatal anxiety, and a lower availability of appropriate obstetric healthcare, which we also observed in our study. Moreover, in Rauf et al.'s study, women experienced increased levels of fear for their own health, as well as that of their baby's, which was also an important aspect in our study [18]. Dunkel Shetter et al. emphasized that anxiety and stress during pregnancy are risk factors for negative outcomes for both mothers and children. Depression and post-traumatic stress disorder most often concern the perinatal period, i.e., 4–6 weeks after delivery [19]. As shown in a recent study, increased levels of anxiety scores were strongly associated with SARS-CoV-2 infection during pregnancy [20].

Due to the forced separation from the father of the child, some needs and expectations of women during pregnancy and childbirth were compromised. The patients mainly regretted limited participation of their partners in maternity care appointments and their absence during delivery. Before the outbreak of the pandemic, patients were able to freely use medical care in the company of a life partner. As showed by Cheng et al., the role of a partner in the care for a pregnant woman is crucial. Among others, low partner support was associated with higher pregnancy-related anxiety [21]. However, in our study, the lack of partner's support was not intended but forced by sanitary restrictions (involuntary separation). Perhaps, for this reason, the absence of a partner during antenatal care generated the sense of injustice and anger among our responders. The systematic review of Antoniou et al. established that a correlation between the support from the partner and prenatal mental disorders and anxiety in women was common [22].

This is in concord with a previous study, showing that the presence of a partner during labor increases positive birth experiences. The partner provides support and assistance to

the pregnant woman during childbirth, reducing her anxiety. The presence of a known and trusted person in the delivery room is essential for most first-time delivery patients [23].

Finally, research shows that when crises are affecting society at large, support and planning are needed for pregnant women, who are a particularly vulnerable [24]. What we propose as the conclusions of our study, is a list of recommendations to such effect.

5. Conclusions

The pandemic turned out to have a significant impact on the quality of life and experiences of pregnant women who participated in our study, especially those of a younger age. During pregnancy, higher levels of anxiety and stress are observed. Among our respondents, the pandemic significantly influenced both, especially due to the perspective of a lonely childbirth and the risk of separation from an infant and its father/partner. It was a new and unpredictable situation that markedly influenced the well-being of pregnant women in all its dimensions: psychological, sociological and even physical. Being pregnant and giving birth to a child is a pivotal life event. Contrary to expectations, pregnant patients were denied access to prenatal care in the partner's company, and family births and appointments were often suspended. Perinatal loneliness was not a choice, but a necessity.

Involuntary separation that occurs widely [25] is a new sociological phenomenon, not only for pregnant women, but also for all patients at the time of the current pandemic. Despite many restrictions, 50.5% (n = 511) of the respondents declared that it did not diminish their joy of pregnancy. In quite important moments, such as the obstetric appointment or delivery, the partner could not take part. As the role of the partner appears to be very important during pregnancy, this forced absence significantly increased the feeling of anxiety. Pregnant women also struggled with a high sense of injustice. However, the decision to get pregnant was seemingly not influenced by the pandemic, with only 8.4% (n = 85) of the respondents declaring it had an impact on their decision. However, this artefact can be explained by the fact that half of the respondents gave birth during the early stage of the pandemic (49.9%, n = 504); thus, the decision to conceive must have preceded its onset.

The fear of contracting COVID-19 during pregnancy (61%, n = 617) and the importance of having a partner present during medical appointments and delivery were highlighted as main challenges. The experiences of the patients we examined have shown that there is still no answer to the loneliness problem in the health care system. Unfortunately, these experiences may have a significant impact on subsequent procreation plans.

While writing this article, we are currently in the middle of the fifth wave of the COVID-19 pandemic. Appointments with a partner are still banned in many places, but more and more people have already been vaccinated against COVID-19. The situation of pregnant women is improving. However, it does not change the fact that patients who have already given birth feel a sense of loss. We hope that with more knowledge about the new SARS-CoV-2 virus and the increasing number of vaccinated people, we will be able to gradually return to the standards of perinatal care from before the outbreak of the pandemic.

Recommendations

Based on our research, we would like to present recommendations that can contribute to better prenatal care for pregnant women and their partners in the current and future pandemics:

Firstly, restriction-related risk calculations should take into account the benefits of accompanied medical appointments and births, which, if possible, should be restored and maintained. These actions can reduce the burden of stress during pregnancy and its consequences. The presence of a partner during pregnancy and childbirth is often paramount for a woman. Additionally, although the partner's participation may pose an

additional risk of infection, available verification methods, e.g., by rapid antigen tests or PCR tests, should be used instead of a top-down ban on joint visits.

Secondly, as shown by research and clinical experience, special situations require special preparation of personnel. It can be achieved through training in response to the specific needs of patients in unusual times. If the situation does not actually allow the patient to contact her family, other forms of contact and new technologies should be used, e.g., video calls, remote or hybrid participation.

Thirdly, psychological care should be provided to all patients and their carers/partners. Psychological consultation should be offered to each patient and her partner. This is especially true of young pregnant women and those giving birth for the first time, and women who are less well-off. This could help identify patients requiring therapy or psychiatric treatment. Moreover, offering patients as much support and empathy as possible is crucial. Most of the respondents indicated insufficient access to information about labor and hospitalization during the pandemic. It is important to improve communication among health professionals and patients. All the regulations related to the necessary restrictions should be presented in simple terms and explained to patients.

All the described solutions should be incorporated into the maternity care plan, which should take into account different possible scenarios in case of an emergency situation.

6. Limitations

Due to epidemic restrictions, the study was largely conducted via the Internet. Only a small number of respondents completed the questionnaire at the clinic (n = 112). Additionally, the selection of the sample was not random, but based on the snowball method. Even though a relatively heterogeneous group was obtained, a large overrepresentation of women with a higher education was observed. Moreover, the study was not preceded by extensive qualitative piloting (only by the doctor's conversations with patients and desk-research). We also have not collected data on the exact time since the birth. However, the questionnaire was administered at the turn of January and February 2021, so all respondents had given birth up to 12 months prior (the pandemic started in Poland in March 2020).

Supplementary Materials: The following supporting information can be downloaded at: https://www.mdpi.com/article/10.3390/ijerph19095081/s1, Table S1. Multivariate linear regression analysis: increased anxiety, Table S2. Multivariate linear regression analysis: anger, Table S3. Multivariate linear regression analysis: feeling of injustice, Table S4. Multivariate linear regression analysis: overwhelming sadness, Table S5. Multivariate linear regression analysis: a sense of loss.

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Conflicts of Interest: The authors declare no conflict of interest.

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COVID-19 Vaccination Status among Pregnant and Postpartum Women—A Cross-Sectional Study on More Than 1000 Individuals

Urszula Nowacka [1,*], Paulina Malarkiewicz [2], Janusz Sierdzinski [3], Aleksandra Januszaniec [1], Szymon Kozłowski [1] and Tadeusz Issat [1]

[1] Department of Obstetrics and Gynecology, Institute of Mother and Child, Kasprzaka 17a, 01-211 Warsaw, Poland; aleksandra.januszaniec@imid.med.pl (A.J.); szymon.kozlowski@imid.med.pl (S.K.); tadeusz.issat@imid.med.pl (T.I.)
[2] Department of Obstetrics and Gynecology, School of Medicine, Collegium Medicum of the University of Warmia and Mazury, Al. Warszawska 30, 10-082 Olsztyn, Poland; p.malarkiewicz@gmail.com
[3] Department of Medical Informatics and Telemedicine, Medical University of Warsaw, Litewska 14/16, 00-581 Warsaw, Poland; jsierdzinski@wum.edu.pl
* Correspondence: ulasarzynska@gmail.com or urszula.nowacka@imid.med.pl; Tel.: +48-22-327-70-44

Abstract: Pregnancy is a well-known factor for vaccine hesitancy and immunization remains the most effective form of prevention against coronavirus disease (COVID-19) related complications. The objective was to estimate vaccine uptake and hesitancy rate, characteristics, and factors contributing to a decision-making process among pregnant and postpartum individuals. This was a prospective cross-sectional study on 1033 pregnant (54.1%) and postpartum (45.9%) women conducted between December 2021 and March 2022 in a tertiary center for maternal–fetal medicine. Logistic regression was used to assess characteristics related to the vaccination decision process. Among responders, 74% were vaccinated and 26% were hesitant (9% planning to vaccinate and 17% totally opposed). Only 59.8% were offered a vaccine by healthcare professionals. Women with higher levels of education (OR 2.26, $p < 0.0001$), who received positive feedback about vaccination (OR 2.74, $p = 0.0172$), or were informed about COVID-19 complications in pregnancy (OR 2.6, $p < 0.0001$) were most likely to accept the vaccination. Hesitancy was associated with multiparity (≥3, OR 4.76, $p = 0.006$), worse educational status (OR 2.29, $p < 0.0001$), and lack of previous COVID-19 infection (OR 1.89, $p < 0.0001$). The most common reason for rejection was insufficient safety data (57%). Understanding factors behind vaccination status is crucial in lowering complications in mothers and newborns and targeted action may facilitate the uptake.

Keywords: COVID-19; pregnancy; vaccination; vaccine uptake; vaccine hesitancy; Tdap vaccine; vaccine; vaccination status; fetus; maternal–fetal medicine

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1. Introduction

Since the beginning of the coronavirus disease (COVID-19) pandemic, pregnant individuals have been assigned to a high-risk group due to resemblance to previous respiratory infection outbreaks, such as severe acute respiratory syndrome (SARS), Middle East respiratory syndrome (MERS) 1–3, and influenza [1]. Various viral infections, which pregnant women are susceptible to, may contribute to unfavorable pregnancy outcomes through numerous molecular mechanisms [2,3]. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection in pregnant women has been linked not only to an increased risk of obstetric complications such as preterm birth and stillbirth but also to hospital and intensive care unit admissions, need for mechanical ventilation, and death, compared to non-pregnant age-matched group [4,5]. This risk can be further multiplied by the presence of chronic comorbidities [5]. Immunization against SARS-CoV-19 remains the most effective form of prevention against COVID-19-related complications [6].

There are two major benefits of vaccinating women in pregnancy: it protects a woman from diseases that she can be particularly susceptible to in the course of gestation, and, indirectly, protects the developing fetus [7]. Additionally, it triggers antibody production, which is transferred through the placenta (IgG) or secreted with breastmilk (IgA) to protect the fetus and infant within the first months of life [7]. The majority of vaccines are not administered until an infant reaches at least 6 weeks of life; therefore, maternal immunization may fill the gap when a baby is immunocompromised [7].

Although initially pregnant women were not offered vaccines due to safety concerns, guidelines from the Centers for Disease Control and Prevention were shortly thereafter changed in favor of immunization [8,9]. The UK recommendation was modified on 30th December 2020 advising vaccine uptake for pregnant women at greater risk of contracting an infection (healthcare workers, frontline staff) or with concomitant risk factors [10]. Shortly thereafter, pregnant individuals were included in vaccination schedules with the rest of the population, and the mRNA vaccines were the preferred products to be administered [10]. The Polish Society of Obstetricians and Gynecologists issued consistent local recommendations on 21 April 2021 [11]. Currently, the majority of the guidelines worldwide indicate that pregnant individuals should be offered the vaccination at the same time as non-pregnant women based on their age and clinical risk group [12]. Having COVID-19 vaccination in pregnancy does not alter perinatal outcomes [13].

COVID-19 vaccine effectiveness in pregnant women is comparable to non-pregnant individuals and the safety data was derived from animal studies as well as from women unaware of pregnancy at the time of vaccination [12]. Moreover, there are emerging pharmacovigilance reports showing no additional adverse events or complications after receiving the vaccine in gestation, with more than 200,000 pregnant individuals vaccinated in the USA to date [14]. Vaccine coverage is known to be substantially lower in pregnant women than in the general female population [12]. Gestation is a well-known factor for vaccine hesitancy, defined as uncertainty or refusal of a vaccine, despite the availability of vaccine services [5] Although professional organizations underline the need for appropriate counseling and shared decision-making provided by healthcare professionals, only about half of the pregnant individuals in the USA are vaccinated for influenza and pertussis every year [5]. Factors associated with hesitancy are minority ethnicity and race, low socioeconomic status, and young age [5,8]. Understanding the lack of acceptability of the COVID-19 vaccine and addressing certain issues is crucial in lowering morbidity and mortality rates in pregnant women, as 98% of expecting individuals admitted to the hospital because of COVID-19 in one of the studies were unvaccinated [15].

The majority of databases do not indicate the number of women vaccinated during pregnancy and very few studies investigate vaccine hesitancy within pregnant individuals [16]. Therefore, the objective of this multi-method study was to investigate vaccine uptake among pregnant and postpartum women as well as associated characteristics and decision-making concerns.

2. Materials and Methods

This was a prospective cross-sectional study about COVID-19 vaccination in pregnancy conducted in a tertiary center for maternal–fetal medicine and obstetrics. Recipients of all sorts of care (emergency services, online consultations, midwifery care, general obstetrics, and maternal–fetal medicine) provided by the site were offered to take part in an anonymous survey. Depending on patients' preferences and a form of consultation, a paper form or an online link was provided. The survey assessed sociodemographic factors and perceptions about vaccination for COVID-19, influenza, and pertussis (tetanus, diphtheria, and acellular component of pertussis—Tdap), as recommended by local guidelines. The questionnaire addressed uptake, views on vaccination in pregnancy, prior exposure, and critical factors in the decision-making process. The survey was open to eligible beneficiaries of care provided by the Institute of Mother and Child in Warsaw, Poland, between

December 2021 and February 2022. The study was approved by the Institute of Mother and Child Research Ethics Committee (Appendix to Approval No 49/2020).

2.1. Participants

All the participants were ≥18 years old. The inclusion criteria were women fluent in their native language with a singleton, uncomplicated pregnancy, and 10–42 weeks' gestation confirmed by a healthcare professional, or up to 6 weeks postpartum. All the women were invited to fill in an anonymous questionnaire. Participants gave written informed consent (paper version) or agreed to undergo an online survey, which had a consent part with a tick box, to take part in the study.

2.2. Recruitment

Eligible participants were recruited in person or while telephone calls by the research staff. Before claiming a voluntary wish to participate, every woman was described with a purpose and formula. A piece of information revealing a thorough description of the study, the main researcher's bio, and contact details in case of any further queries, feedback, and complaints was placed on the cover page of the folder, followed by written consent (paper version). The online questionnaire was prefaced with an informational part about the study purpose and data management and a tick box to consent for the study. Therefore, all of the enrolled participants gave informed consent. All the partially filled forms (lacking date of birth and pregnancy dating status) were discarded from further analysis. No extra appointments were scheduled after the completion of the questionnaire.

2.3. Design

The survey formula was designed by a multidisciplinary team that mainly consisted of midwives and physicians and was based on our previous study on generalized anxiety in the pandemic [17]. The survey had two parts:

Demographic part: questions related to demography, pregnancy order, education, socioeconomic factors, profession, chronic conditions, cigarette use;

Vaccination part: questions related to uptake, personal views on COVID-19 vaccination, healthcare professionals' and women's environment's influence, influenza, and pertussis vaccination status.

All the data was collected anonymously, paper questionnaires were stored separately from the consent forms. There were 24 questions in total, the number of questions answered depended on the vaccination status. Vaccine hesitancy was previously defined by the World Health Organization as uncertainty or refusal of vaccination, despite the availability of vaccination services [5]. Previous studies focused mostly on hesitancy using a Likert scale [5,8]. To keep the survey as simple and short as possible and also to avoid abandoning it while filling in, we decided on omitting the mentioned part and focused on motives in favor of and against the vaccination. Because our center reports less than 5% of the patients of non-Caucasian origin in general, the race and ethnicity issue was not raised.

2.4. Outcomes

The main objective of the study was to quantitatively assess the vaccination status in pregnant and postpartum women. Secondary outcomes were factors contributing to the decision-making process, such as the influence of healthcare providers and the professional bodies, reasoning for not choosing or choosing the vaccination, as well the time of receiving the vaccination doses (pre-, during, and post-pregnancy). Individuals could choose more than one reason. The survey also focused on sociodemographic factors and views on influenza and pertussis vaccination. The following patient characteristics were assessed: age, parity, place of residence, education, current employment status, financial situation, number of people in the household, chronic diseases, and tobacco use. The second part addressed the "3 Cs" model (complacency, convenience, and confidence) determined by the WHO Vaccine Communications Working Group in order to understand the determinants of

vaccine hesitancy [18]. The assessment included vaccine acceptance, time of administration of the first dose (pre-, during, and post-pregnancy), the total number of doses, COVID-19 exposure, reception of the vaccine by friends and family, and opinion of the healthcare providers (1–4 Likert scale), counseling about the benefits of vaccination, influenza, and pertussis vaccine uptake. The questions regarding factors contributing to the decision-making process were multiple-choice with a possible self-proposed answer.

2.5. Statistical Analysis

All sociodemographic and clinical factors were compared between women who accepted the vaccine and those who rejected it [19]. Logistic regression was used to calculate odds ratios (ORs) between patient characteristics (parity, place of residence, education, history of COVID infection, proposal of vaccination by healthcare professionals, attitude of healthcare professionals towards vaccination, information about risk of infection in pregnancy from healthcare professionals) and COVID-19 acceptance variables [20]. We did not fill in the missing data. Data analysis was performed using SAS statistical software version STAT 9.4 (SAS Institute, Cary, NC, USA). p-values < 0.05 were considered significant and all tests were two-tailed.

3. Results

During the study period, 1033 participants finished the survey—350 papers (33.9%) and 794 electronic (66.1%) forms were completed. A total of 559 (54.1%) women were pregnant and 447 (45.9%) were postpartum (not discharged from hospital after delivery) while completing the form. The group was divided into the following subgroups (Figure 1): (1). vaccinated before pregnancy; (2). vaccinated while pregnant; (3). vaccinated before pregnancy and booster administered while pregnant; (4). planning to vaccinate; (5). unvaccinated. As a result of thorough consideration, we decided to not include in logistic regression individuals planning to vaccinate as their status and the final decision could not be established. Therefore, for further logistic analysis, the following groups emerged: vaccinated (1 + 2 + 3) and unvaccinated (5). The demographics behind the study group are presented in Table 1 and Figure 1.

Table 1. Demographic characteristics of the study group.

	Total (N = 1033)	**COVID-19 Vaccinated (N = 613)**	**COVID-19 Unvaccinated (N = 324)**	**Planning to Vaccinate to COVID-19 (N = 96)**
%	100%	59.3%	31.4%	9.3%
Maternal age, mean (SD)	30.5 (4.1)	31.2 (3.9)	29.4 (4.2)	30.4 (4.1)
Mean gestational age (SD)	27.1 (9.1)	29.2 (8.4)	24.4 (9.1)	27.7 (11.1)
Mean gestational age at delivery (SD)	38.9 (2.4)	38.9 (2.6)	38.7 (2.2)	39.0 (1.4)
Number of pregnancies mean (SD)	1.68 (0.9)	1.7 (0.9)	1.63 (0.9)	1.71 (0.9)
Mean parity (SD)	0.89 (1.2)	0.94 (0.9)	1.73 (1.8)	1.09 (0.9)

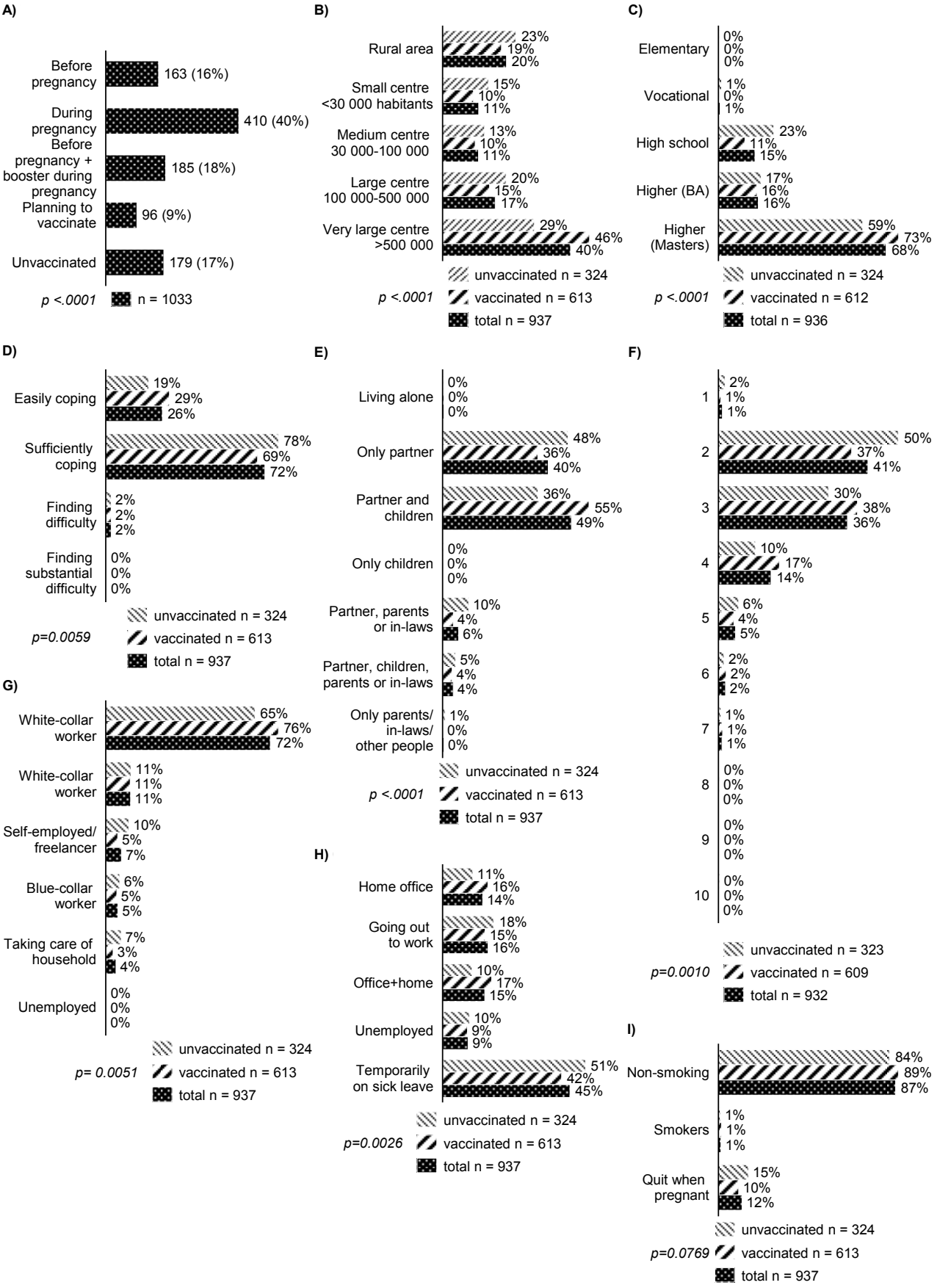


Figure 1. *Cont.*

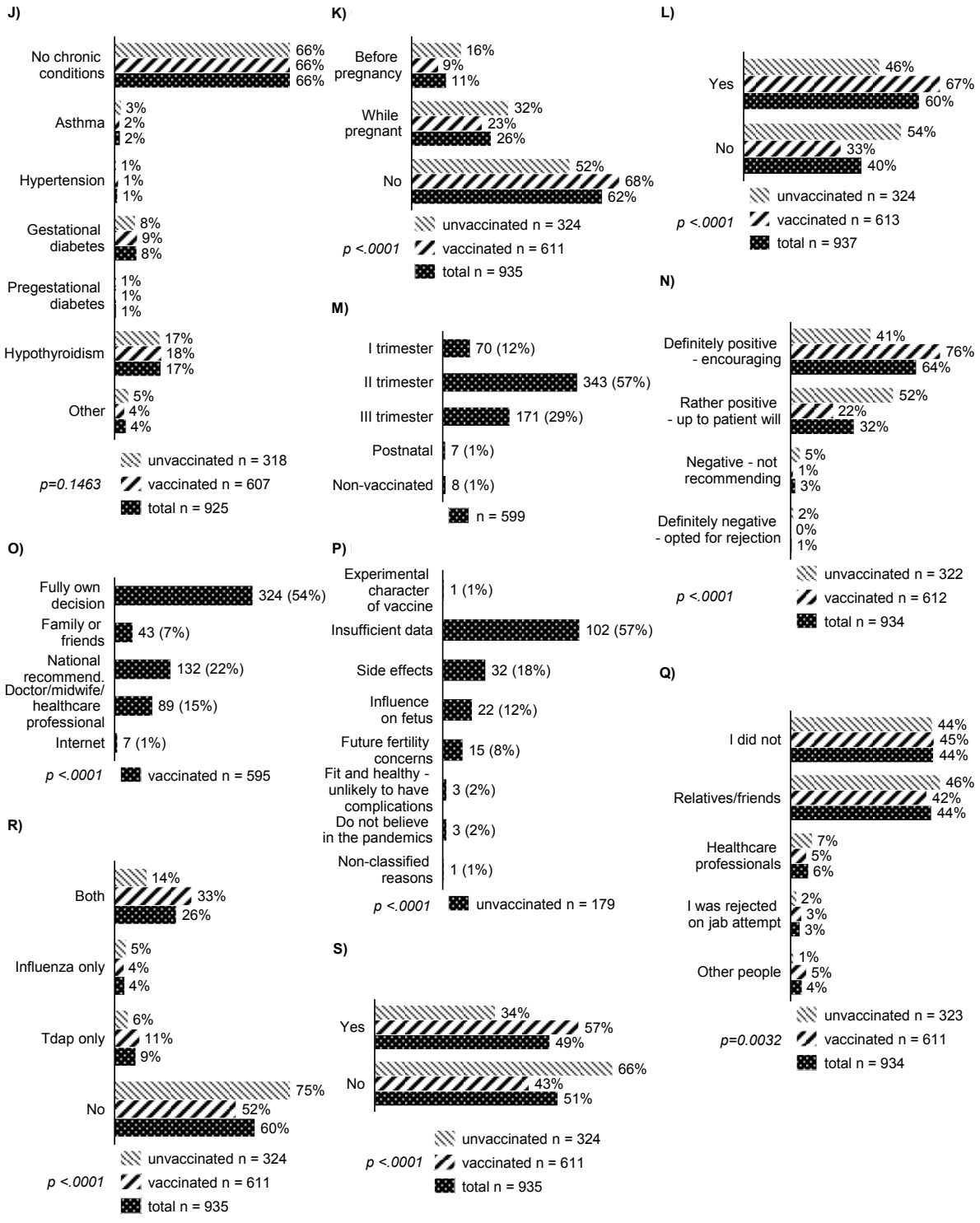


Figure 1. Questions asked in the survey. (**A**) Vaccination distribution among respondents; (**B**) Place of residence; (**C**) Education; (**D**) Financial situation; (**E**) Household description; (**F**) Number of people in the household; (**G**) Profession; (**H**) Current job status; (**I**) Smoking status; (**J**) Chronic conditions; (**K**) COVID-19 infection status; (**L**) Were you offered a COVID-19 vaccine by your doctor/midwife? (**M**) Vaccination first dose timing; (**N**) What was your doctor/midwife attitude towards COVID-19 vaccination? (**O**) Who helped you in making decision about vaccination? (**P**) Reason for vaccine rejection; (**Q**) Who did you experience negative attitude towards vaccination from? (**R**) Were you oferred a Tdap and/or influenza vaccine? (**S**) Did you doctor/midwife inform you about increased risk of COVID-19 infection in pregnancy?

The mean age of participants was 30.5 years (SD 4.1). A total of 40.5% were living in very large urban centers with more than 500,000 inhabitants. A total of 68.2% had a master's degree and almost all (97.5%) reported their financial status to be very good or sufficient to cover all their expenses. Almost three-quarters (72.2%) constituted office and administrative workers and nearly half (45.4%) were on sick leave while pregnant. A total of 34.9% reported some kind of a chronic illness with hypothyroidism being the most common (17.2%). A total of 1.3% reported tobacco usage while pregnant. A total of 37.7% of responders had a history of COVID-19 infection with a quarter (26%) reported during pregnancy. A total of 74% of responders were vaccinated against COVID-19 (16% before pregnancy; 40% during pregnancy; 18% before pregnancy with a booster while pregnant); 26% were hesitant (9% planning to vaccinate and 17% totally opposed). For women vaccinated in pregnancy, the second trimester was the most common time for administration (43.6%). Only 59.8% of individuals were offered a COVID-19 vaccination by their doctors or midwives but only less than 1% (0.8%) were actively discouraged from vaccination by a healthcare professional. A total of 54.6% claimed that the decision about vaccine intake was totally a personal one, 43.7% experienced negative feedback about vaccination in pregnancy from relatives or friends, and 5.6% from healthcare professionals. A total of 56% of unvaccinated responders rejected vaccination due to insufficient clinical data and only 12.1% due to a potential influence on the developing fetus. The majority of individuals (60.1%) were not offered a Tdap/influenza vaccine and only 13.9% of postpartum women completed both Tdap and influenza vaccination. Less than half (48.9%) were informed about the increased risk of COVID-19/pertussis/influenza infection in pregnancy.

With regards to logistic regression, factors associated with higher odds of vaccine acceptance were nulliparity (OR 1.74; 95% CI 1.43–2.12), living in a large or a very large city (OR 1.51; 95% CI 1.09–2.1), higher education (master's and bachelor's, OR 2.26; 95% CI 1.53–3.34), history of COVID-19 infection (OR 1.92; 95% CI 1.43–2.59), a vaccination offer from a doctor or midwife (OR 1.54; 95% CI 1.11–2.12), positive attitude of a doctor/midwife towards the vaccination (OR 2.74; 95% CI 1.2–6.29), and information received from a doctor/midwife about a high risk of COVID-19 complications (OR 2.146; 95% CI 1.55–2.8) (Table 2). Factors associated with higher odds of rejection were having children: 3 versus 0 (OR 4.8; 95% CI 2.0–11.6), 3 versus 1 (OR 2.15; 95% CI 0.89–5.2), 3 versus 2 (OR 1.78; 95% CI 0.69–4.59), lower educational status (elementary + vocational + high school) (OR 2.29; 95% CI 1.55–3.39), and lack of COVID infection in the past (OR 1.89; 95% CI 1.4–2.55) (Table 3)

Table 2. Multivariate analysis of predictors of COVID-19 vaccine acceptance. OR: ordinal odds ratio. 95% CI: 95% confidence interval.

Effect	OR	95% CI	Standard Error	*p*-Value
Parity 0 vs. ≥1	1.74	1.43–2.12	0.0995	<0.0001
Place of residence (medium center vs. small + rural area)	1.15	0.7–1.88	0.2517	0.5852
Place of residence (large and very large center vs. small + rural area)	1.51	1.09–2.1	0.1673	0.0137
Education (masters + bachelor's vs. elementary + vocational + high school)	2.26	1.53–3.34	0.1988	<0.0001
History of COVID-19 infection	1.92	1.43–2.59	0.1527	<0.0001
Vaccination offered by a doctor/midwife	1.54	1.11–2.12	0.1657	0.0097
Positive attitude of a doctor/midwife towards vaccination	2.74	1.2–6.29	0.4234	0.0172
Information from a doctor/midwife about a high risk of COVID-19 complications	2.15	1.55–2.98	0.1672	<0.0001

Table 3. Multivariate analysis of predictors of COVID-19 vaccine rejection. OR: ordinal odds ratio. 95% CI: 95% confidence interval.

Effect	OR	95% CI	Standard Error	*p*-Value
Having children 3 and more vs. 0	4.8	2.0–11.6	0.4522	0.0006
Having children 3 vs. 1	2.15	0.89–5.2	0.4502	0.0896
Having children 3 vs. 2	1.78	0.69–4.59	0.4825	0.2318
Education (elementary + vocational + high school vs. master's + bachelor's)	2.29	1.55–3.39	0.1990	<0.0001
Lack of COVID-19 infection in the past	1.89	1.4–2.55	0.1533	<0.0001

4. Discussion

4.1. Main Findings

There are a few main findings of this study: (1) the majority of pregnant/postpartum women in the sample were fully vaccinated, (2) in 40% of cases, the COVID-19 vaccine was not offered by a healthcare professional, and only half were informed about the increased risk of severe infection, (3) recommendations issued by the professional body helped to convince almost a quarter of women, (4) the most common reason for vaccination rejection was insufficient data, (5) in 60% of cases, the influenza/Tdap vaccine were not offered by healthcare professionals, (6) factors associated with vaccine acceptance were nulliparity, living in big urban centers, higher education, history of COVID infection, vaccination offer from a doctor/midwife, positive attitude of a doctor/midwife towards the vaccination, and information received from a doctor/midwife about the high risk of COVID-19 complications, and (7) factors associated with rejection were having children, lower educational status and lack of COVID infection in the past.

Our study of 1033 women investigated attitudes towards the COVID-19 vaccine during the fourth wave of the pandemic, at the time when the Omicron variant dominated, almost a year after immunization in pregnancy have been introduced. Important conclusions from studies had been already available at the start of the survey—almost all hospitalized pregnant individuals were unvaccinated and 17% of the total critically ill patients in English hospitals on extra corporeal membrane oxygenation (ECMO) therapy were pregnant women [8].

Our study found quite a substantial level of hesitancy among pregnant and postpartum women, which is consistent with pre-existing data [5,12]. Expecting individuals are likely to be in opposition to vaccination compared to age-matched non-pregnant peers [21]. Moreover, the results are highlighting the role of healthcare providers in vaccine hesitancy. Unfortunately, 40% and 60% of women in the cohort were not offered immunization against COVID-19 and influenza/pertussis, respectively, by their doctors and midwives. The extent of this phenomenon is worrying as the main focus is usually put on patients' willingness rather than on the information provided by the physicians.

This factor may trigger placing vaccination matters on the interview checklist for doctors and midwives. Educational actions may also play an important role in modifying those unexpected factors, as vaccine hesitancy among healthcare providers is not as rare as expected [22].

The most common reason for vaccine rejection in our study was insufficient data on vaccine safety in pregnancy. Therefore, counseling based on safety for unborn babies and infants may be more effective than emphasizing a disease threat to the mother, an issue previously described [23]. Presenting supportive data on facilitating a newborn's humoral response and antibodies transfer through the placenta and breast milk may also make hesitancy less probable [24]. Another reason for hesitancy included concerns regarding safety related to insufficient data and lack of reliable publications. It suggests that this factor is modifiable, as around a fifth of individuals could change the decision as more data will emerge from different cohorts over time. In the meantime, pregnant and breastfeeding

individuals could be inclined towards a decision using guidelines, which play a great role in a decision-making process, as professional recommendations helped more than a fifth of responders. Healthcare providers should introduce this important matter while counseling, as access to recommendations may not be universal, especially within deprived groups. Ethnic minority background is a well-known factor not only for COVID-19, Tdap, and influenza vaccine hesitancy but also for dying from COVID-19 [5,8]. We are currently experiencing the biggest migration crisis in Europe since World War II—the number of people fleeing from Ukraine is estimated to be almost 4 million at the moment, with the vast majority choosing Poland as a main destination [25]. Only 35% of the Ukrainian population was vaccinated, with boosters administered to only 1.7% [26]. Therefore, as people arriving in Poland are mostly women of reproductive age, we can anticipate an increase in infection numbers among pregnant individuals in the future. This should trigger informational actions at every level of healthcare, encouraging women to undergo the immunization process. Moreover, uptake should be promoted not only within a group without an initial vaccination course—secondary hesitancy related to individuals vaccinated before pregnancy with two doses needs promotion of a booster dose to be taken in the course of pregnancy.

Vaccine hesitancy/negative vaccination status in pregnancy in our study was lower than reported by other authors (37.9% according to Skirrow et al. [8]; 40.7%—Saitoh et al. [27]; 46%—Kiefer et al. [21]; 50.9%—Hosokawa et al. [16]; 61.2%—DesJardin et al. [28]; 89.5%—Blakeway et al. [13]). This was mostly due to the earlier stages of the COVID-19 pandemic while completing the data collection in the above-mentioned studies. Similarly, safety concerns and insufficient data were raised as one of the main reasons for rejection [5,8,27,29]. In the majority of available cohorts, resembling risk factors for vaccine rejection were mentioned—less formal education/lower socioeconomic status and multiparity are the most common ones [5,13,28]. This brings the conclusion that the reasons behind vaccine hesitancy are quite universal in different settings which may facilitate widespread campaigns for expecting mothers and those planning to get pregnant.

4.2. Strengths and Limitations

There are certain limitations to be mentioned. This study presents a sample of pregnant and postpartum women involved to a different extent in care at a single, centrally located unit, in a large urban center, with possible selection bias. Therefore, the study was offered mainly to an educated, modern, urban population, which might have been reflected in the vaccine acceptance rate and the conclusion could be drawn with limited generalizability. In terms of survey development, we did not use a validated questionnaire, but the formula was based rather on our previous study and clinical practice [17]. The acceptance was assessed at a single point in time, and it may be fluctuating throughout pregnancy—hesitating individuals could have eventually accepted the vaccination. As the Tdap vaccine is administered in the third trimester, some responders at the early stages of pregnancy might not have had a discussion on the matter with a healthcare professional. The questionnaire does not assess the rate of COVID-19 infection and complications among the closest family and friends, as well as personal beliefs and values. The study was totally dependent on patients' self-reported vaccination status and the information was not verified in any databases.

Numerous assets prove the study as valuable research. In order to increase the number of responders, two methods of data collection were introduced. The online questionnaire was powered by the biggest platform for survey conduction in our country, which allowed the Internet version to be approachable and easily navigable on any electronic device for the responder's convenience. The final number of interviewees exceeded a thousand, making it a considerable basis for analysis. The survey was fully anonymous, which helped in obtaining reliable answers. As the demographic structure shows, the responders were embedded in different backgrounds, including a whole range of ages, income levels, and pregnancy stages.

The study took place in the middle of the fourth wave of the pandemic and Poland is placed among the most COVID-stricken countries in Europe, with 15,478 confirmed cases per 100,000 to date [30]. Enrollment took place a few months after the release of numerous recommendations and all the participants had a chance to undergo vaccination.

5. Conclusions

Understanding factors facilitating the decision as well as the obstacles is critical for implementing prevention methods [31]. These factors may serve as the basis for further campaigns and interventions to increase COVID-19 vaccine acceptance, especially among vulnerable populations.

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Informed Consent Statement: Informed consent was obtained from all subjects involved in the study. Written informed consent has been obtained from the patients to publish this paper.

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Intrahepatic Cholestasis of Pregnancy during COVID-19 Pandemic

Paulina Malarkiewicz [1,*], Urszula Nowacka [2], Aleksandra Januszaniec [2], Alicja Mankiewicz [3], Szymon Kozłowski [2] and Tadeusz Issat [2]

[1] Department of Obstetrics and Gynecology, School of Medicine, Collegium Medicum of the University of Warmia and Mazury, al. Warszawska 30, 10-082 Olsztyn, Poland
[2] Department of Obstetrics and Gynecology, Institute of Mother and Child, Kasprzaka 17a, 01-211 Warsaw, Poland
[3] Department of Obstetrics and Gynecology, Olsztyn Specialist Hospital, Żołnierska 18; 10-561 Olsztyn, Poland
* Correspondence: paulina.malarkiewicz@uwm.edu.pl

Abstract: *Background and Objectives*: Intrahepatic cholestasis of pregnancy (ICP) stands as one of the most prevalent concerns in maternal–fetal medicine, presenting a significant risk to fetal health and often associated with liver dysfunction. Concurrently, the coronavirus-19 (COVID-19) infection can lead to hepatic cell injury through both direct and indirect pathways. Hypothetically, these two conditions may coincide, influencing each other. This study aimed to comparatively assess the incidence and severity of ICP before and during the COVID-19 pandemic. *Methods*: A retrospective cohort study was conducted, comparing the incidence and severity of ICP between January 2018 and February 2020 (pre-COVID-19 period) and March 2020 to March 2022 (COVID-19 period) across two hospitals, encompassing 7799 deliveries. The diagnosis of ICP was established using the ICD-10 code and defined as total bile acids (BA) levels $\geq$ 10 µmol/L. Statistical analysis included descriptive statistics, Chi-square and Mann–Whitney U tests, as well as multiple or logistic regression analysis. *Results*: A total of 226 cases of ICP were identified. The incidence of mild cholestasis (BA < 40 µmol/L) was lower during the pandemic compared to before (3% before versus 2%, $p < 0.05$), while the incidence of moderate and severe ICP remained unchanged (0.6% before vs. 0.4%, $p = 0.2$). Overall, the total incidence of ICP was lower during the pandemic (3.6% before versus 2.4%, $p = 0.01$). No significant differences were observed in severity (as defined by BA and liver function test levels), rates of caesarean section, or neonatal birth weights. *Conclusions*: During the COVID-19 pandemic, the total incidence of ICP appeared to be lower. However, this reduction was primarily observed in cases of mild ICP, potentially indicating challenges in detection or reduced access to medical services during this period. The incidence of moderate and severe ICP remained unchanged, suggesting that these forms of the condition were unaffected by the pandemic's circumstances.

Keywords: intrahepatic cholestasis of pregnancy; pregnancy; COVID-19; liver damage; maternal–fetal medicine; pandemic

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1. Introduction

Intrahepatic cholestasis of pregnancy (ICP) is the most common reversible hepatic disorder related to pregnancy, characterized by pruritus in the absence of a primary skin condition, with onset predominantly in the third trimester [1]. Although the condition poses a mild risk to a woman, it carries a major risk for a fetus, including preterm delivery, meconium-stained amniotic fluid, and stillbirth [2]. The prevalence differs among ethnic groups and geographical regions, varying between 0.3 and 5.6% of pregnancies. Incidence seems to be more pronounced in winter months [3,4]. Around 25% of women may experience itching in pregnancy; therefore, diagnosis cannot be made based on symptoms alone [5]. To diagnose ICP, maternal bile acid levels must exceed a given threshold, recently established by the Royal College of Obstetricians and Gynaecologists to be 19 µmol/L,

while non-fasting [1]. The commonly used upper limit of bile acids of 10 µmol/L currently lies within the normal range, and concomitant itching should be diagnosed as gestational pruritus [6]. Although elevated liver enzymes may be increased simultaneously, they do not reflect the risk of fetal demise as bile acids do [1,7]. According to a meta-analysis with aggregate and individual patient data, the risk of stillbirth in singleton pregnancies is associated with the maximum total bile acid concentration, especially over 100 µmol/L [8]. Ursodeoxycholic acid, a first-line treatment until now, does not reduce adverse perinatal outcomes and may even increase the readings of the bile acids [9]. ICP is associated with pre-existing metabolic derangements, including maternal dyslipidemia and glucose intolerance; therefore, it is often diagnosed with gestational diabetes mellitus and pre-eclampsia [4].

Although ICP typically resolves almost immediately after delivery, there is growing evidence that the diagnosis increases the risk of maternal hepatobiliary disease later in life, in addition to susceptibility to hepatobiliary cancer, immune, and cardiovascular diseases. Therefore, women who have had a pregnancy complicated by ICP should undergo close follow-up [4]. Apart from the fetal adverse outcomes, in utero exposure to high bile acids, exacerbated by the reversal of the trans-placental gradient of bile acid concentrations, may play a role in fetal programming and metabolic changes later in life, which can already be observed in adolescence [4]. All these factors emphasize the importance of a definitive diagnosis of ICP during pregnancy.

The coronavirus (COVID-19, COVID) pandemic outbreak significantly transformed medical management, affecting not only general medical conditions but also psychological aspects [10]. Due to multiple immune system alterations during gestation, pregnant individuals become susceptible to pathogens, especially respiratory viruses, making them a high-risk group during the pandemic [11]. Maternal infection during pregnancy increases the risk of adverse outcomes, particularly preterm birth [12]. Although vaccination against COVID-19 has an established role in preventing maternal and fetal complications, the rate of hesitancy among pregnant women remains substantial [11]. Among the myriad effects on various targets, SARS-CoV2 has been found to cause direct and indirect hepatic injury, especially in those with chronic illnesses and immunocompromised states [13]. COVID-19 disease is associated with hepatic involvement not only during the initial infection but also as sequelae [14–16]. Regarding pregnancy, elevated liver enzymes have been reported in patients with COVID infection and intrahepatic cholestasis of pregnancy (ICP) compared to non-infected women [17]. As some authors have hypothesized a possible correlation–causation sequence between maternal COVID-19 and ICP [18], the objective of this study was to assess the incidence and course of ICP before and during the pandemic era.

2. Materials and Methods

This was a retrospective, two-site cohort study conducted at tertiary centers for maternal–fetal medicine and obstetrics, specifically the Institute of Mother and Child (Instytut Matki i Dziecka, IMiD) in Warsaw, Poland, and Olsztyn Specialist Hospital (WSS) in Olsztyn, Poland, among individuals receiving prenatal and/or perinatal care at general obstetrics, midwifery, and maternal–fetal medicine clinics. We included pregnant women with maximum total bile acids levels $\geq$ 10 µmol/L (according to the national guideline at that time) without underlying liver disease, in singleton and twin pregnancies [19]. Multiples with more than two fetuses, individuals with underlying chronic liver diseases, pre-eclampsia, hemolysis, elevated liver enzymes and low platelet counts (HELLP), viral hepatitis, and acute fatty liver of pregnancy were excluded from this study. Eligible individuals were enrolled from March 2020 (the onset of the pandemic in Poland) to March 2022. The pre-COVID-19 period was defined as January 2018 to February 2020. Data details were obtained from hospital data systems, and the following aspects were collected: parity, COVID infection during pregnancy (prior to the diagnosis of ICP), confirmed by a positive result of real-time polymerase chain reaction (RT-PCR) from nasopharyngeal and/or oropharyngeal samples derived from a national registry, maximum levels of ALT (alanine transaminase), ASP (aspartate transaminase), and BA (bile acids); pharmacological

agents (ursodeoxycholic acid and others), gestational age at diagnosis, number of fetuses, concomitant diseases, labor (spontaneous, induced, no labor), delivery (vaginal, elective cesarean, emergency cesarean), gestational age at delivery, and birth weight. This study was approved by the Bioethics Committee at the Faculty of Medicine, University of Warmia and Mazury (approval number: 13/2022). The analysis was conducted in two variants. Variant one (1) compared the incidence of ICP and characteristics of the ICP patients of the pre-pandemic period with the pandemic period. The start date of the COVID-19 period in Poland was established as 4 March 2020 (the date of the first confirmed case in Poland). In variant two (2), the analysis compared ICP patients with a confirmed diagnosis of COVID-19 with the remaining number of ICP patients, regardless of the period. Statistical analysis was performed using Statistica 13.0, employing descriptive statistics, statistical tests, and multiple regression analysis (for endpoints with a quantitative variable) or logistic regression analysis (for endpoints with a binary variable). Categorized variables were compared using the χ^2 test, and quantitative variables were compared using the Mann–Whitney test. The level of significance was established as 0.05.

3. Results

The analysis included 226 ethnically homogeneous women with ICP. Among these, 122 (54%) delivered during the pre-pandemic period and 104 (46%) during the pandemic period. A positive COVID-19 test result was obtained by 25 women (11% of the total number and 24% of the pandemic period). The basic characteristics of the study group are shown in Table 1. Patients with ICP in both analyzed variants did not differ in maternal age, primiparity, time of ICP diagnosis, and rate of concomitant gestational diabetes mellitus (GDM). The comparative characteristics of the study population are shown in Table 2. There were 3397 deliveries before and 4402 during the pandemic era in both centers. The incidence of ICP seemed to be lower during the pandemic (3.6% versus 2.4%, $p = 0.01$). Although the incidence of mild ICP (BA < 40 μmol/L) appeared to be lower during the pandemic (3% before vs. 2%, $p < 0.05$), the incidence of moderate and severe ICP (BA $\geq$ 40 μmol/L) remained stable (0.6% before vs. 0.4% during the pandemic, $p = 0.2$).

Table 1. Baseline characteristics of the study population.

		Variant 1			Variant 2		
	General	**Childbirth before the Pandemic**	**Childbirth during the Pandemic**	***p*-Value for the Difference**	**No History of COVID-19**	**History of COVID-19**	***p*-Value for the Difference**
Age (years): median IQR	32.4 (29.0–36.4)	32.4 (29.6–36.3)	32.6 (28.9–36.4)	0.979 *	32.5 (29.1–36.4)	31.3 (28.9–36.5)	0.571 *
Primiparity	101 (51%)	59 (52%)	42 (51%)	0.873 **	88 (51%)	13 (52%)	0.938 **
Diagnosis of ICP—days before the due date	34 (21–50)	34 (22–46)	33 (21–55)	0.801 *	33 (21–48.5)	40 (22–58.0)	0.118 *
Twins, N (%)	16 (7%)	9 (7%)	7 (7%)	0.970 **	1 (3%)	15 (7%)	0.412 **
Gestational diabetes, N (%)	65 (29%)	32 (25%)	33 (32%)	0.209 **	57(28%)	8(27%)	0.872

* Mann–Whitney U test; ** Pearson's chi-square test.

No differences were observed between levels of BA, AST, and ALT between the groups, both on admission and at maximum reported levels (Table 2). ICP was the main reason for the induction of labor (IOL) and cesarean section in a similar proportion of patients with ICP before and during the pandemic (52% vs. 53%, $p = 0.778$), as well as in those with COVID infection during pregnancy and those without (53% vs. 50%, $p = 0.782$). The rate of instrumental deliveries (cesarean sections, vacuum-assisted deliveries, or forceps deliveries) also remained similar (47% before and 48% during the pandemic, $p = 0.905$; 53% without COVID and 50% with COVID infection; $p = 0.782$). There were no differences observed in birth weight between both variants (3250 g before and 3180 g during the pandemic, $p = 0.263$; 3135 g without COVID and 3200 g with COVID infection; $p = 0.925$).

Table 2. Main outcomes of this study.

	Before Pandemic [&]	**%** [$]	**In the Pandemic** [&]	**%** [$]	***p* Value for the Difference**	**Without COVID-19** [$]	**%** [$]	**COVID-19 +** [$]	**%** [$]	***p* Value for the Difference**
Number of deliveries	3397		4402		0.0013 **					
Incidence of ICP	122	3.59% (359/10,000)	104	2.36% (236/10,000)		201		25		
Moderate ICP ≥ 40 µmol/L	19	0.559%	16	0.36%	0.1913 **	31		4		
Mild ICP < 40 µmol/L	103	3.03%	88	2.00%	0.0035 **	170		21		
BA (µmol/L) -on admission -maximum	13.9 18.5	(9.0–30.0) (10.9–40.9)	16.9 22.5	(10.2–31.5) (12.2–44.5)	0.301 * 0.178 *	14.6 20.2	(9.4–31.1) (13.3–42.3)	15.1 19.5	(9.6–28.0) 12.6–43.0)	0.972 * 0.600 *
ALT (U/l) -on admission -maximum	132.0 158.0	(57.0–122.0) (76.0–301.0)	132.5 154.5	(65.0–269.0) (86.0–359.0)	0.833 * 0.522 *	139.0 157.0	(65.0–276.0) (84.0–325.0)	101.0 149.5	(51.0–215.0) (66.0–288.0)	0.171 * 0.528 *
AST (U/l) -on admission -maximum	83.5 99.0	(41.0–149.5) (50.5–173.5)	78.5 95.0	(47.0–151.0) (51.0–198.0)	0.793 * 0.631 *	84.5 100.0	(41.0–153.5) (57.0–178.0)	63.5 84.5	(47.0–94.0) (49.0–176.0)	0.435 * 0.666 *
ICP as a main indication for IOL or CS	67	51.5%	55	53.4%	0.778 **	107	(52.7%)	15	(50.0%)	0.782 **
Cesarean section/vacuum assisted/forceps delivery	58	47%	47	48%	0.905 **	88	(45%)	17	59%	0.199 **
Birth weight (grams)	3250	(2800–3600)	3180	(2720–3540)	0.263 *	3135	(2650–3750)	3200	(2770–3540)	0.925 *

ICP—intrahepatic cholestasis of pregnancy; BA—bile acids; AST—aspartate aminotransferase; ALT—alanine aminotransferase; IOL—induction of labor; CS—cesarean section; [&] number for categorical variables, median for continuous variables; [$] percent for categorical variables, interquartile range for continuous variables; * Mann–Whitney U test; ** Pearson's chi-square test.

4. Discussion

This study yielded several findings as follows: (1) the incidence of total ICP appeared to be lower during the pandemic; (2) the incidence of mild ICP seemed to be lower during the pandemic; (3) the incidence of moderate and severe ICP remained stable; (4) the timing of ICP diagnosis did not differ between the pre-pandemic and pandemic periods, nor between COVID-infected and non-infected patients; (5) the levels of BA, ALT, and AST remained similar in patients with ICP during both the pre-pandemic and pandemic periods, and between COVID-infected and non-infected patients; (6) ICP was the reason for induction of labor/cesarean section in a similar proportion of patients in both scenarios; (7) the rate of instrumental deliveries remained similar during both the pre-pandemic and pandemic periods, and between COVID-infected and non-infected patients; and (8) neonatal birth weight did not differ between the groups in both scenarios.

The healthcare crisis induced by COVID-19 has underscored the necessity for an interdisciplinary approach to identify potential sequelae and risk groups for complications.

Multiple studies have reported altered liver function tests (LFTs) not only in the general population infected with COVID-19, but also in pregnant individuals [20–22]. Approximately 3–5% of pregnancies can result in abnormal LFTs in the second half of pregnancy due to various reasons besides ICP, such as pre-eclampsia, hemolysis, elevated liver enzymes and low platelet counts, viral hepatitis, or acute fatty liver of pregnancy [23]. These conditions were excluded from our study.

Our data revealed a lower incidence of ICP during the pandemic compared to the pre-pandemic period. Due to the scarcity of available studies, drawing a definitive conclusion is challenging; however, this observation specifically pertains to patients with mild ICP. We hypothesize that women with only a mild increase in BA levels and subtle symptoms may not have sought medical advice due to the COVID-19 pandemic. According to the Centers for Disease Control and Prevention (CDC), 40% of adults were avoiding medical care due to concerns related to COVID infection [24]. While there is one study showing contradictory results, comparing both conclusions is challenging due to different ethnic settings and timing [25]. In the latest study on the topic by Holden et al., the authors reported an increased incidence of COVID infection in women with ICP. Among 596 patients, all individuals who tested positive for COVID-19 with ICP were Hispanic [26].

The severity of ICP, as reflected by liver function test (LFT) results, did not differ between the pre-pandemic and pandemic periods, nor between COVID-infected and non-infected patients. Partially similar results were reported by Soffer et al. [27]. In their study, BA levels remained stable, and AST and ALT levels were higher during the pandemic, regardless of ongoing detected COVID infection. However, it is extremely difficult to compare the infection rate within the pregnant population of the studies. Although it has been established that COVID infection could lead to hepatic involvement and subsequent injury, the similar BA results suggest a different pathophysiological mechanism. Januszewski et al. [28] examined the liver damage profile in COVID-infected pregnant patients of an identical ethnic background to our study population. In that group, the median level of bile acid in COVID-infected patients was higher compared to healthy pregnant individuals, but levels were within normal ranges even in women with the most severe course of COVID-19 disease. In those with liver injury, the type of damage was rather hepatotoxic than cholestatic. The liver damage in COVID-19 patients is multifactorial, as the spectrum of liver injury in COVID infection ranges from direct infection with SARS-CoV-2 to indirect involvement by systemic inflammation, hypoxic changes, iatrogenic causes such as medications, intensive care procedures, and exacerbation of underlying liver disease [8]. Cai et al. [20] suggested that liver injury and abnormal tests are mostly due to certain medications used during hospitalization; therefore, it may apply mostly to patients with severe COVID-19. Both sites of this study did not accept pregnant patients with severe COVID-19, thus there was a possible sampling bias. Moreover, age is a known risk factor for a severe COVID-19 course, and in general, the pregnant population consists of healthy individuals in reproductive age [29]. Another factor is that different medications are avoided by physicians in the pregnant population, or, although prescribed, they are avoided by the women themselves [30].

There are several limitations to this retrospective study in addition to those mentioned above. Many patients could have had asymptomatic COVID infection or may have intentionally avoided testing. We lack details of the total number of COVID infections in all pregnancies due to differing universal testing policies between the study sites. We did not include information about vaccination as the majority of data were collected before universal vaccination recommendations for pregnant women [11]. Moreover, we did not stratify the severity of COVID infection. The time span between COVID infection and ICP was not reported, as infection at any point during pregnancy was taken into account. We did not separate a subgroup of ongoing infection and ICP.

Nevertheless, there are several strengths to mention. We included only patients who fulfilled laboratory criteria for ICP. The presence of COVID infection was derived from the national registry, where only confirmed laboratory results from swabs taken by

healthcare professionals were entered. All patients fulfilling the ICP criteria were tested for COVID-19 upon admission. To our knowledge, this is the first full-text study comparing the characteristics of ICP before and during the pandemic in our geographical and racial setting. However, it is evident that the existing literature lacks large-scale studies examining the incidence of cholestasis of pregnancy, particularly in diverse settings. To address this gap, comprehensive analyses of individual patient data from various settings are imperative.

5. Conclusions

During the COVID-19 pandemic, the total incidence of ICP appeared to be lower. However, this decrease was primarily observed in cases of mild ICP, suggesting potential challenges in detection or avoidance of medical services during the pandemic, as these patients may have had less intense symptoms.

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ANKIETA PRACY ZAWODOWEJ I NAUKOWEJ

1. Imię i nazwisko: Paulina Małgorzata Malarkiewicz
2. Posiadane dyplomy, stopnie naukowe – z podaniem nazwy, miejsca i roku

Szkoła średnia:
1998-2002 II Liceum Ogólnokształcące w Olsztynie im. Konstantego Ildefonsa Gałczyńskiego

Studia medyczne:
2002 r.-2005r Uniwersytet Medyczny w Białymstoku, Wydział Lekarski z Oddziałem Stomatologii
2005 r.-2010r Gdański Uniwersytet Medyczny, Wydział Lekarski, kierunek lekarski

Staż podyplomowy:
2010 r.-2011 r. Wojewódzki Szpital Specjalistyczny w Olsztynie

Szkolenia specjalizacyjne:
2011 r.-2018 r. Szkolenie specjalizacyjne w trybie rezydenckim w zakresie położnictwa i ginekologii Wojewódzki Szpital Specjalistyczny w Olsztynie
2018 r. – uzyskanie tytułu specjalisty położnictwa i ginekologii
2019 r.-2023 r. Szkolenie specjalizacyjne w trybie pozarezydenckim z genetyki klinicznej w Instytucie Matki i Dziecka w Warszawie
2023 r. – Uzyskanie tytułu specjalisty genetyki klinicznej
2024 r. – obecnie. Szkolenie specjalizacyjne w trybie pozarezydenckim z ginekologii onkologicznej w Wojewódzkim Szpitalu Specjalistycznym w Olsztynie

3. Informacje o dotychczasowym zatrudnieniu w jednostkach naukowych:

2011 r.- 2013 r. Asystent, Pracownik naukowo-dydaktyczny Katedry Farmakologii i Toksykologii Uniwersytetu Warmińsko-Mazurskiego w Olsztynie
2014 r. – obecnie. Asystent, Katedra Ginekologii i Położnictwa Uniwersytetu Warmińsko-Mazurskiego w Olsztynie, z Oddziałem Angielskojęzycznym

4. Analiza bibliometryczna dorobku:

Mój całkowity dorobek naukowy to 7 artykułów o sumarycznym Impact Factor (IF) 13.500 przy punktacji MNiSW/KBN 535

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   Polskie Towarzystwo Ginekologów i Położników

   Polskie Towarzystwo Genetyki Człowieka

6. Działalność dydaktyczna

Prowadzenie zajęć ze studentami polsko- i angielskojęzycznymi na Uniwersytecie Warmińsko-Mazurskim w Olsztynie od 2011r

OŚWIADCZENIA WSPÓŁAUTORÓW

Załącznik nr 5 do Załącznika nr 1
do Uchwały Nr 362
Senatu Uniwersytetu Warmińsko-Mazurskiego w Olsztynie
z dnia 27 czerwca 2023 roku
wprowadzającej procedurę postępowania
w sprawie nadania stopnia doktora

Olsztyn, 17-09-2024
(miejscowość, data)

dr Stanisław Maksymowicz
(tytuł zawodowy/stopień/tytuł naukowy, imię i nazwisko)

Przewodniczący Rady Naukowej Dyscypliny
Prof. dr hab. n.med. Marcin Mycko
Uniwersytetu Warmińsko-Mazurskiego w Olsztynie

OŚWIADCZENIE
współautora

Oświadczam, że w pracy pod tytułem „Mothers Loneliness: Involuntary Separation of Pregnant Women in Maternity Care Settings and Its Effects on the Experience of Mothers during the COVID-19 Pandemic" (Paulina Malarkiewicz, Stanisław Maksymowicz, Maria Libura, 2022, Mothers Loneliness: Involuntary Separation of Pregnant Women in Maternity Care Settings and Its Effects on the Experience of Mothera during the COVID-19 Pandemic ‚International Journal of Environmental Research and Public Health (IJERPH)) mój wkład merytoryczny w jej przygotowanie polegał na: opracowaniu koncepcji i metodologii oraz opracowaniu i interptetacji wyników pracy.

Jednocześnie wyrażam zgodę na przedłożenie w/w pracy przez Paulinę Malarkiewicz jako część rozprawy doktorskiej w formie spójnego tematycznie zbioru artykułów naukowych opublikowanych w czasopismach naukowych.

Oświadczam, iż samodzielna i możliwa do wyodrębnienia część ww. pracy wykazuje indywidualny wkład kandydata Pauliny Malarkiewicz polegający na opracowaniu koncepcji i metodologii, opracowaniu i interpretacji wyników pracy, pisanie i przygotowanie oryginalnego projektu, recenzji i redakcji, analizie statystycznej.

Stanisław Maksymowicz
podpis

Załącznik nr 5 do Załącznika nr 1
do Uchwały Nr 362
Senatu Uniwersytetu Warmińsko-Mazurskiego w Olsztynie
z dnia 27 czerwca 2023 roku
wprowadzającej procedurę postępowania
w sprawie nadania stopnia doktora

Warszawa 01.09.2024
(miejscowość, data)

Dr hab. n.med. Janusz Sieradziński

Przewodniczący Rady Naukowej Dyscypliny
Prof. dr hab. n.med. Marcin Mycko
Uniwersytetu Warmińsko-Mazurskiego w Olsztynie

OŚWIADCZENIE
współautor

Oświadczam, że w pracy pod tytułem „COVID-19 Vaccination Status among Pregnant and Postpartum Women ---A Cross-Sectional Study on More Than 1000 Individuals" (Urszula Nowacka, Paulina Malarkiewicz, Janusz Sieradziński, Aleksandra Januszaniec, Szymon Kozłowski, Tadeusz Issat, 2022, COVID-19 Vaccination Status among Pregnant and Postpartum Women ---A Cross-Sectional Study on More Than 1000 Individuals, Vaccines) mój wkład merytoryczny w jej przygotowanie polegał na: analizie statystycznej.

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polegający na opracowaniu koncepcji, selekcji danych i interpretacji wyników pracy.

Janusz Sieradziński
podpis

Załącznik nr 5 do Załącznika nr 1
do Uchwały Nr 362
Senatu Uniwersytetu Warmińsko-Mazurskiego w Olsztynie
z dnia 27 czerwca 2023 roku
wprowadzającej procedurę postępowania
w sprawie nadania stopnia doktora

Olsztyn 1.06.2024
(miejscowość, data)

Lekarz Alicja Mankiewicz

Przewodniczący Rady Naukowej Dyscypliny
Prof. dr hab. n.med. Marcin Mycko
Uniwersytetu Warmińsko-Mazurskiego w Olsztynie

OŚWIADCZENIE
współautor

Oświadczam, że w pracy pod tytułem „Intrahepatic Cholestasis of Pregnancy during COVID-19 Pandemic" (Paulina Malarkiewicz, Urszula Nowacka, Aleksandra Januszaniec, Alicja Mankiewicz, Szymon Kozłowski, Tadeusz Issat, 2024, Intrahepatic Cholestasis of Pregnancy during COVID-19 Pandemic, Medicina) mój wkład merytoryczny w jej przygotowanie polegał na: zbieraniu i selekcji danych

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Alicja Mankiewicz
podpis

PODPIS ZAUFANY
MARIA
LIBURA
19.09.2024 09:13:13 (GMT+2)
Dokument podpisany elektronicznie
podpisem zaufanym

Załącznik nr 5 do Załącznika nr 1
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Senatu Uniwersytetu Warmińsko-Mazurskiego
z dnia 27 czerwca 2023 roku
wprowadzającej procedurę postępowania
w sprawie nadania stopnia doktora

Olsztyn, 18 września 2024
(miejscowość, data)

dr n.med. i n. o zdr. Maria Libura
(tytuł zawodowy/stopień/tytuł naukowy, imię i nazwisko)

Przewodniczący Rady Naukowej Dyscypliny
Prof. dr hab. n.med. Marcin Mycko
Uniwersytetu Warmińsko-Mazurskiego w Olsztynie

OŚWIADCZENIE
współautor

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.....
podpis

Załącznik nr 5 do Załącznika nr 1
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z dnia 27 czerwca 2023 roku
wprowadzającej procedurę postępowania
w sprawie nadania stopnia doktora

Warszawa, 12.09.2024
(miejscowość, data)

Dr n. med. Urszula Nowacka
Białostocka 20 03-741 Warszawa
90120702960
urszula.nowacka@imid.med.pl
tel.509487056

Przewodniczący Rady Naukowej Dyscypliny
Prof. dr hab. n.med. Marcin Mycko
Uniwersytetu Warmińsko-Mazurskiego w Olsztynie

OŚWIADCZENIE
współautor

Oświadczam, że w pracy pod tytułem „Intrahepatic Cholestasis of Pregnancy during COVID-19 Pandemic" (Paulina Malarkiewicz, Urszula Nowacka, Aleksandra Januszaniec, Alicja Mankiewicz, Szymon Kozłowski, Tadeusz Issat, 2024, Intrahepatic Cholestasis of Pregnancy during COVID-19 Pandemic, Medicina) mój wkład merytoryczny w jej przygotowanie polegał na: opracowaniu metodologii, zarządzanie projektem, recenzji i redakcji.

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podpis

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w sprawie nadania stopnia doktora

Warszawa, 12.09.2024
(miejscowość, data)

Dr n.med. Urszula Nowacka
Białostocka 20 03-741 Warszawa
90120702960
urszula.nowacka@imid.med.pl
tel.509487056

Przewodniczący Rady Naukowej Dyscypliny
Prof. dr hab. n.med. Marcin Mycko
Uniwersytetu Warmińsko-Mazurskiego w Olsztynie

OŚWIADCZENIE
współautor

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podpis

Załącznik nr 5 do Załącznika nr 1
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z dnia 27 czerwca 2023 roku
wprowadzającej procedurę postępowania
w sprawie nadania stopnia doktora

Warszawa 11.09.2024r

Lekarz Szymon Kozłowski
Pesel: 79022413932
ul. Gwiaździsta 15/308
01-651 Warszawa
szykozlowski@imid.med.pl
48668192709

Przewodniczący Rady Naukowej Dyscypliny
Prof. dr hab. n.med. Marcin Mycko
Uniwersytetu Warmińsko-Mazurskiego w Olsztynie

OŚWIADCZENIE
współautor

Oświadczam, że w pracy pod tytułem „Intrahepatic Cholestasis of Pregnancy during COVID-19 Pandemic" (Paulina Malarkiewicz, Urszula Nowacka, Aleksandra Januszaniec, Alicja Mankiewicz, Szymon Kozłowski, Tadeusz Issat, 2024, Intrahepatic Cholestasis of Pregnancy during COVID-19 Pandemic, Medicina) mój wkład merytoryczny w jej przygotowanie polegał na: zbieraniu i selekcji danych

Jednocześnie wyrażam zgodę na przedłożenie w/w pracy przez Paulinę Malarkiewicz jako część rozprawy doktorskiej w formie spójnego tematycznie zbioru artykułów naukowych opublikowanych w czasopismach naukowych.

Oświadczam, iż samodzielna i możliwa do wyodrębnienia część ww. pracy wykazuje indywidualny wkład kandydata Pauliny Malarkiewicz
polegający na opracowaniu koncepcji, metodologii, analizie danych i interpretacji wyników, analizie statystycznej oraz przygotowaniu tekstu.

.....
podpis

Załącznik nr 5 do Załącznika nr 1
do Uchwały Nr 362
Senatu Uniwersytetu Warmińsko-Mazurskiego w Olsztynie
z dnia 27 czerwca 2023 roku
wprowadzającej procedurę postępowania
w sprawie nadania stopnia doktora

Warszawa 11.09.2024r

Lekarz Szymon Kozłowski
Pesel: 79022413932
ul. Gwiaździsta 15/308
01-651 Warszawa
szykozlowski@imid.med.pl
48668192709

Przewodniczący Rady Naukowej Dyscypliny
Prof. dr hab. n.med. Marcin Mycko
Uniwersytetu Warmińsko-Mazurskiego w Olsztynie

OŚWIADCZENIE
współautor

Oświadczam, że w pracy pod tytułem „COVID-19 Vaccination Status among Pregnant and Postpartum Women ---A Cross-Sectional Study on More Than 1000 Individuals" (Urszula Nowacka, Paulina Malarkiewicz, Janusz Sieradziński, Aleksandra Januszaniec, Szymon Kozłowski, Tadeusz Issat, 2022, COVID-19 Vaccination Status among Pregnant and Postpartum Women ---A Cross-Sectional Study on More Than 1000 Individuals, Vaccines) mój wkład merytoryczny w jej przygotowanie polegał na: weryfikacji danych.

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.....
podpis

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z dnia 27 czerwca 2023 roku
wprowadzającej procedurę postępowania
w sprawie nadania stopnia doktora

Warszawa, 11/09/24r
(miejscowość, data)

Lekarz Aleksandra Januszaniec
Adres: ul.Nowy Świat 54/56 m.2 00-363 Warszawa
Pesel: 93061211067
e-mail: o.januszaniec@gmail.com
tel: (+48) 513091325

Przewodniczący Rady Naukowej Dyscypliny
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Uniwersytetu Warmińsko-Mazurskiego w Olsztynie

OŚWIADCZENIE
współautor

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polegający na opracowaniu koncepcji, metodologii, analizie danych i interpretacji wyników, analizie statystycznej oraz przygotowaniu tekstu.

A. Januszaniec
podpis

Załącznik nr 5 do Załącznika nr 1
do Uchwały Nr 362
Senatu Uniwersytetu Warmińsko-Mazurskiego w Olsztynie
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w sprawie nadania stopnia doktora

Warszawa 11/09/24
(miejscowość, data)

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Adres: ul.Nowy Świat 54/56 m.2 00-363 Warszawa
Pesel: 93061211067
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OŚWIADCZENIE
współautor

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Jednocześnie wyrażam zgodę na przedłożenie w/w pracy przez Paulinę Malarkiewicz jako część rozprawy doktorskiej w formie spójnego tematycznie zbioru artykułów naukowych opublikowanych w czasopismach naukowych.

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A. Januszaniec
podpis

Załącznik nr 5 do Załącznika nr 1
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z dnia 27 czerwca 2023 roku
wprowadzającej procedurę postępowania
w sprawie nadania stopnia doktora

Warszawa dn. 10.09.2024r

dr hab.n.med Tadeusz issat prof. IMID
ul. Złoczowska 12/6 03-972 Warszawa
Pesel: 80060905655
tadissat@imid.med.pl
Tel: 605682305

Przewodniczący Rady Naukowej Dyscypliny
Prof. dr hab. n.med. Marcin Mycko
Uniwersytetu Warmińsko-Mazurskiego w Olsztynie

OŚWIADCZENIE
współautor

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Jednocześnie wyrażam zgodę na przedłożenie w/w pracy przez Paulinę Malarkiewicz jako część rozprawy doktorskiej w formie spójnego tematycznie zbioru artykułów naukowych opublikowanych w czasopismach naukowych.

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Jednocześnie wyrażam zgodę na przedłożenie w/w pracy przez Paulinę Malarkiewicz jako część rozprawy doktorskiej w formie spójnego tematycznie zbioru artykułów naukowych opublikowanych w czasopismach naukowych.

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.....
podpis

Olsztyn, dn. 11.09.2024 r.

lek. Paulina Malarkiewicz
Katedra Ginekologii i Położnictwa
Wydział Lekarski
Uniwersytet Warmińsko-Mazurski w Olsztynie

Analiza bibliometryczna dorobku naukowego lek. Pauliny Malarkiewicz (*na podstawie bazy Bibliografii Publikacji Pracowników Uniwersytetu Warmińsko-Mazurskiego w Olsztynie***)**

1. Analiza cytowań

Lp.	Rok	Tytuł publikacji	Ilość cytowań w bazie Web of Science Core Collection	Ilość cytowań w bazie Scopus
1.	**2022**	**Mothers Loneliness: Involuntary Separation of Pregnant Women in Maternity Care Settings and Its Effects on the Experience of Mothers during the COVID-19 Pandemic** *International Journal of Environmental Research and Public Health*	3	4
2.	**2022**	**Overcoming therapeutic nihilism. Breaking bad news of amyotrophic lateral sclerosis - a patient-centred perspective in rare diseases** *Neurological Sciences*	5	6
3.	**2022**	**COVID-19 Vaccination Status among Pregnant and Postpartum Women-A Cross-Sectional Study on More Than 1000 Individuals** *Vaccines*	8	7
4.	**2019**	**Co nasi pacjenci wiedzą na temat suplementacji? Edukacja pacjentek oddziału położniczego jako nowe potencjalne zadanie farmaceuty szpitalnego - badanie wstępne/** What	-	1

		do our patients know about supplementation? Education of patients in the obstetric ward as a new potential task for a hospital pharmacist - preliminary study *Farmacja Polska*		
		Suma cytowań:	**16**	**18**

Podsumowanie cytowań w bazie Web of Science Core Collection w dniu 11.09.2024 r.:

liczba prac cytowanych = 3	**liczba cytowań = 16**	**Index Hirscha (Index h) = 3**

Podsumowanie cytowań w bazie Scopus w dniu 11.09.2024 r.:

liczba prac cytowanych = 4	**liczba cytowań = 18**	**Index Hirscha (Index h) = 3**

2. Zestawienie punktacyjne całego dorobku publikacyjnego

	łączna liczba prac	liczba prac z IF	liczba prac z punktacją MNiSW	łączna wartość IF	łączna wartość punktacji MNiSW
ogółem	**7**	**3**	**7**	**13.500**	**535**
artykuł w czasopiśmie polskim	3	0	3	0.000	145
artykuł w czasopiśmie zagranicznym	4	3	4	13.500	390

3. Wykaz publikacji:

1.
IDT: 0000091276.
Rok: 2024
Autorzy: Malarkiewicz Paulina, Nowacka Urszula, Januszaniec Aleksandra, Mankiewicz Alicja, Kozłowski Szymon, Issat Tadeusz
Tytuł oryginału: Intrahepatic Cholestasis of Pregnancy during COVID-19 Pandemic
Czasopismo: Medicina-Lithuania
Opis fizyczny: 2024, 60 (4), s. 1-7 ; bibliogr. 30 poz. ; nr art. 676
Adres url: https://www.mdpi.com/1648-9144/60/4/676
p-ISSN: 1648-9144
Język publikacji: ENG
DOI: 10.3390/medicina60040676
open-access-text-version: FINAL_PUBLISHED

open-access-licence: CC-BY
open-access-release-time: AT_PUBLICATION
open-access-article-mode: OPEN_JOURNAL
Data ukazania się publikacji: 2024.09.09
Charakt. formalna: artykuł w czasopiśmie zagranicznym
Charakt. merytoryczna: praca oryginalna
Inne bazy podające opis: Web of Science Core Collection ; Scopus
Impact Factor: 2.400
Punktacja MNiSW: 40.000
Dyscypliny czasopisma na podstawie wykazu MNiSW z 2024.01.05: inżynieria biomedyczna;biologia medyczna;nauki farmaceutyczne;nauki medyczne;nauki o zdrowiu;nauki o rodzinie;biotechnologia;weterynaria
Tytuł czasopisma w wykazie MNiSW z 2024.01.05: Medicina-Lithuania
Afiliacja: Malarkiewicz Paulina [*] 0000-0002-7677-3910 5e70921c878c28a04739014e;338;23, Nowacka Urszula [ ];000;000, Januszaniec Aleksandra [ ];000;000, Mankiewicz Alicja [ ];000;000, Kozłowski Szymon [ ];000;000, Issat Tadeusz [ ];000;000

2.
IDT: 0000081278.
Rok: 2022
Autorzy: Malarkiewicz Paulina, Maksymowicz Stanisław, Libura Maria
Tytuł oryginału: Mothers Loneliness: Involuntary Separation of Pregnant Women in Maternity Care Settings and Its Effects on the Experience of Mothers during the COVID-19 Pandemic
Czasopismo: International Journal of Environmental Research and Public Health
Opis fizyczny: 2022, 19 (9), s. 1-13 ; bibliogr. 25 poz. ; nr art. 5081
Adres url: https://www.mdpi.com/1660-4601/19/9/5081
p-ISSN: 1660-4601
Język publikacji: ENG
DOI: 10.3390/ijerph19095081
open-access-text-version: FINAL_PUBLISHED
open-access-licence: CC-BY
open-access-release-time: AT_PUBLICATION
open-access-article-mode: OPEN_JOURNAL
Data ukazania się publikacji: 2022.10.10
Charakt. formalna: artykuł w czasopiśmie zagranicznym
Charakt. merytoryczna: praca oryginalna
Inne bazy podające opis: Web of Science Core Collection ; Scopus
Punktacja MNiSW: 140.000
Dyscypliny czasopisma na podstawie wykazu MNiSW z 2024.01.05: architektura i urbanistyka;inżynieria lądowa, geodezja i transport;inżynieria środowiska, górnictwo i energetyka;biologia medyczna;nauki farmaceutyczne;nauki medyczne;nauki o kulturze fizycznej;nauki o zdrowiu;nauki leśne;rolnictwo i ogrodnictwo;technologia żywności i żywienia;geografia społeczno-ekonomiczna i gospodarka przestrzenna;nauki o zarządzaniu i jakości;nauki prawne;biotechnologia;nauki biologiczne;nauki chemiczne;weterynaria
Tytuł czasopisma w wykazie MNiSW z 2024.01.05: International Journal of Environmental Research and Public Health

Afiliacja: Malarkiewicz Paulina [*] 0000-0002-7677-3910 5e70921c878c28a04739014e;338;23, Maksymowicz Stanisław [*] 0000-0002-6606-9575 5e709457878c28a0473bad72;449;25, Libura Maria [*] 0000-0001-6242-0674;504;23

3.
IDT: 0000078939.
Rok: 2022
Autorzy: Maksymowicz Stanisław, Libura Maria, Malarkiewicz Paulina
Tytuł oryginału: Overcoming therapeutic nihilism. Breaking bad news of amyotrophic lateral sclerosis - a patient-centred perspective in rare diseases
Czasopismo: Neurological Sciences
Opis fizyczny: 2022, 43 (7), s. 4257-4265 ; bibliogr. 32 poz.
Adres url: https://doi.org/10.1007/s10072-022-05931-1
p-ISSN: 1590-1874
Język publikacji: ENG
DOI: 10.1007/s10072-022-05931-1
open-access-text-version: FINAL_PUBLISHED
open-access-licence: CC-BY
open-access-release-time: AFTER_PUBLICATION
open-access-months: 1
open-access-article-mode: OPEN_JOURNAL
Data ukazania się publikacji: 2022.03.03
Charakt. formalna: artykuł w czasopiśmie zagranicznym
Charakt. merytoryczna: praca oryginalna
Inne bazy podające opis: Web of Science Core Collection ; Scopus
Impact Factor: 3.300
Punktacja MNiSW: 70.000
Dyscypliny czasopisma na podstawie wykazu MNiSW z 2024.01.05: inżynieria biomedyczna;biologia medyczna;nauki farmaceutyczne;nauki medyczne;nauki o kulturze fizycznej;nauki o zdrowiu;nauki o rodzinie;biotechnologia;nauki biologiczne;weterynaria
Tytuł czasopisma w wykazie MNiSW z 2024.01.05: NEUROLOGICAL SCIENCES
Afiliacja: Maksymowicz Stanisław [*] 0000-0002-6606-9575 5e709457878c28a0473bad72;449;25, **Libura Maria** [*] 0000-0001-6242-0674;504;23, Malarkiewicz Paulina [*] 0000-0002-7677-3910 5e70921c878c28a04739014e;338;23

4.
IDT: 0000081279.
Rok: 2022
Autorzy: Nowacka Urszula, Malarkiewicz Paulina, Sierdziński Janusz, Januszaniec Aleksandra, Kozłowski Szymon, Issat Tadeusz
Tytuł oryginału: COVID-19 Vaccination Status among Pregnant and Postpartum Women-A Cross-Sectional Study on More Than 1000 Individuals
Czasopismo: Vaccines
Opis fizyczny: 2022, 10 (8), s. 1-11 ; bibliogr. 31 poz. ; nr art. 1179
Adres url: https://www.mdpi.com/2076-393X/10/8/1179
p-ISSN: 2076-393X

Język publikacji: ENG
DOI: 10.3390/vaccines10081179
open-access-text-version: FINAL_PUBLISHED
open-access-licence: CC-BY
open-access-release-time: AT_PUBLICATION
open-access-article-mode: OPEN_JOURNAL
Data ukazania się publikacji: 2022.10.10
Charakt. formalna: artykuł w czasopiśmie zagranicznym
Charakt. merytoryczna: praca oryginalna
Inne bazy podające opis: Web of Science Core Collection ; Scopus
Impact Factor: 7.800
Punktacja MNiSW: 140.000
Dyscypliny czasopisma na podstawie wykazu MNiSW z 2024.01.05: inżynieria biomedyczna;biologia medyczna;nauki farmaceutyczne;nauki medyczne;nauki o zdrowiu;biotechnologia;nauki biologiczne;weterynaria
Tytuł czasopisma w wykazie MNiSW z 2024.01.05: Vaccines
Afiliacja: Nowacka Urszula [ ];000;000, Malarkiewicz Paulina [*] 0000-0002-7677-3910 5e70921c878c28a04739014e;338;23, Sierdziński Janusz [ ];000;000, Januszaniec Aleksandra [ ];000;000, Kozłowski Szymon [ ];000;000, Issat Tadeusz [ ];000;000

5.
IDT: 0000078797.
Rok: 2021
Autorzy: Malarkiewicz Paulina, Rottke Włodzimierz
Tytuł oryginału: Nietrzymanie moczu u kobiet
Tytuł równoległy: Urinary incontinence in women
Czasopismo: Medycyna po Dyplomie
Opis fizyczny: 2021 (11), s. 40-44 ; bibliogr. 18 poz.
Adres url: https://podyplomie.pl/mpd/categories/2298
p-ISSN: 1231-1812
Język publikacji: POL
Data ukazania się publikacji: 2022.02.22
Charakt. formalna: artykuł w czasopiśmie polskim
Charakt. merytoryczna: praca oryginalna
Punktacja MNiSW: 5.000
Uwaga dot. automatycznej identyfikacji: Niezidentyfikowano na wykazie dyscyplin
Afiliacja: Malarkiewicz Paulina [*] 0000-0002-7677-3910 5e70921c878c28a04739014e;338;23, Rottke Włodzimierz [*] 5f801f07085dcb410a25ec30;338;23

6.
IDT: 0000062108.
Rok: 2019
Autorzy: Puchała Łukasz, Malarkiewicz Paulina, Wiśniewski Łukasz, Kalinowski Marek, Grzegorzewski Waldemar J.
Tytuł oryginału: Co nasi pacjenci wiedzą na temat suplementacji? Edukacja pacjentek oddziału położniczego jako nowe potencjalne zadanie farmaceuty szpitalnego - badanie wstępne

Tytuł równoległy: What do our patients know about supplementation? Education of patients in the obstetric ward as a new potential task for a hospital pharmacist - preliminary study
Czasopismo: Farmacja Polska
Opis fizyczny: 2019, 75 (5), s. 238-241 ; bibliogr. 9 poz.
p-ISSN: 0014-8261
Język publikacji: POL
DOI: 10.32383/farmpol/116228
Data ukazania się publikacji: 2019.05.15
Charakt. formalna: artykuł w czasopiśmie polskim
Charakt. merytoryczna: praca oryginalna
Inne bazy podające opis: Scopus
Punktacja MNiSW: 70.000
Dyscypliny czasopisma na podstawie wykazu MNiSW z 2024.01.05: biologia medyczna;nauki farmaceutyczne;biotechnologia
Tytuł czasopisma w wykazie MNiSW z 2024.01.05: Farmacja Polska
Afiliacja: Puchała Łukasz [*] 0000-0003-0009-947X 5e7094af878c28a0473c19de;336;23, Malarkiewicz Paulina [*] 0000-0002-7677-3910 5e70921c878c28a04739014e;363;23, Wiśniewski Łukasz [ ];000;000, Kalinowski Marek [ ];000;000, Grzegorzewski Waldemar J. [ ] 0000-0002-3522-1327 905637;000;000

7.
IDT: 0000061231.
Rok: 2019
Autorzy: Puchała Łukasz, Malarkiewicz Paulina, Grzegorzewski Waldemar J.
Tytuł oryginału: Współpraca lekarza i farmaceuty w zakresie optymalizacji farmakoterapii w trakcie doustnego leczenia niepłodności u kobiet. Stan badań klinicznych oceniających skuteczności składników suplementów diety stosowanych w trakcie leczenia niepłodności
Tytuł równoległy: Cooperation between a doctor and a pharmacist in the field of optimalization of pharmacotherapy during oral infertility treatment in women. Status of clinical trials evaluating effectiveness of the components of dietary supplements used during infertility treatment
Czasopismo: Farmacja Polska
Opis fizyczny: 2019, 75 (3), s. 125-128 ; bibliogr. 14 poz.
Adres url: https://www.ptfarm.pl/en/wydawnictwa/czasopisma/farmacja-polska/103/-/28012
p-ISSN: 0014-8261
Język publikacji: POL
Data ukazania się publikacji: 2019.04.23
Charakt. formalna: artykuł w czasopiśmie polskim
Charakt. merytoryczna: praca przeglądowa
Inne bazy podające opis: Scopus
Punktacja MNiSW: 70.000
Dyscypliny czasopisma na podstawie wykazu MNiSW z 2024.01.05: biologia medyczna;nauki farmaceutyczne;biotechnologia
Tytuł czasopisma w wykazie MNiSW z 2024.01.05: Farmacja Polska
Afiliacja: Puchała Łukasz [*] 0000-0003-0009-947X 5e7094af878c28a0473c19de;324;24, Malarkiewicz Paulina [*] 0000-0002-7677-3910 5e70921c878c28a04739014e;338;23, Grzegorzewski Waldemar J. [ ] 0000-0002-3522-1327 905637;000;000