UNIWERSYTET MEDYCZNY
IM. PIASTÓW ŚLĄSKICH WE WROCŁAWIU

Praca doktorska

BARIERY I CZYNNIKI UŁATWIAJĄCE WDRAŻANIE INNOWACYJNYCH INTERWENCJI W ZAKRESIE E-ZDROWIA NA POZIOMIE MIKRO-, MEZO- I MAKROREGIONALNYM W RAMACH POLSKIEGO SYSTEMU OPIEKI ZDROWOTNEJ I SPOŁECZNEJ

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Podziękowania

Przede wszystkim pragnę podziękować mojej Promotor prof. dr hab. Donacie Kurpas
za bezcenne sugestie i uwagi przekazywane w dużym spokoju. Dziękuję za cierpliwość, wspieranie mnie
w trudnych momentach i za wszelką pomoc i pracę jaką włożyła w powstanie tego doktoratu
a przede wszystkim za obdarzenie mnie ogromnym zaufaniem.

„Jeśli posiadasz wiedzę, pozwól, by inni mogli od niej zapalić swoje świece.”
Margaret Fuller

Dziękuję mojej kochanej Rodzinie i Przyjaciołom za niezachwianą wiarę we mnie
i powodzenie tego przedsięwzięcia.
Dziękuję zwłaszcza mojemu mężowi Krzysztofowi, na którego zawsze mogłam liczyć, który
mnie wspierał i niejednokrotnie odciążał mnie w obowiązkach rodzicielskich.

Spis treści

I. Wykaz publikacji będących podstawą rozprawy doktorskiej

Wyniki pracy badawczej zostały ujęte w cyklu trzech publikacji, stanowiących podstawę niniejszej rozprawy doktorskiej. Doktorantka w każdej z nich jest pierwszym autorem:

1. **Stefanicka-Wojtas, D.**; Kurpas, D. eHealth and mHealth in Chronic Diseases—Identification of Barriers, Existing Solutions, and Promoters Based on a Survey of EU Stakeholders Involved in Regions4PerMed (H2020). *J. Pers. Med.* **2022**, 12, 467. https://doi.org/10.3390/jpm12030467
   5 Year Impact Factor: 4.005
   2021 Journal Impact Factor: 3.508
   Punkty MEIN: 70

2. **Stefanicka-Wojtas, D.**; Kurpas, D. Barriers and Facilitators to the Implementation of Personalised Medicine across Europe. *J. Pers. Med.* 2023, *13*, **2023**. https://doi.org/10.3390/jpm13020203
   5 Year Impact Factor: 4.005
   2021 Journal Impact Factor: 3.508
   Punkty MEIN: 70

3. **Stefanicka-Wojtas, D.**; Kurpas, D. Personalised Medicine—Implementation to the Healthcare System in Europe (Focus Group Discussions). *J. Pers. Med*. **2023**, 13, 380. https://doi.org/10.3390/jpm13030380
   5 Year Impact Factor: 4.005
   2021 Journal Impact Factor: 3.508
   Punkty MEIN: 70

II. Streszczenie

Wstęp

Medycyna personalizowana (PM – ang. *Personalised Medicine*), do której zaliczamy e-zdrowie (elektroniczne usługi zdrowotne) i m-zdrowie (mobilne usługi zdrowotne), oznacza leczenie dostosowane do cech, potrzeb i preferencji pacjenta. Kategoryzuje ona pacjentów według ryzyka rozwoju określonej choroby lub stopnia odpowiedzi na dane leczenie przy użyciu odpowiednich markerów diagnostycznych. PM ma na celu zwiększenie kontroli nad optymalizacją wyników leczenia i precyzji leczenia, a także poprawę przewidywania chorób.

Inteligentne i zorganizowane podejście jest niezbędne do zapewnienia jakości i długoterminowej rentowności europejskich systemów opieki zdrowotnej oraz włączenia PM do praktyki klinicznej. Ma to zasadnicze znaczenie dla kształtowania przyszłości opieki zdrowotnej i społecznej w Europie.

Dynamiczny rozwój PM jest coraz bardziej widoczny ze względu na coraz wyraźniejszy wpływ indywidualnych cech na przebieg choroby i skuteczność leków. Dzięki PM ludzie są bliżej dokładniejszej, bardziej przewidywalnej i silniejszej opieki zdrowotnej oraz społecznej dostosowanej do indywidualnych pacjentów.

Pomimo pojawienia się PM jako nowatorskiego podejścia do leczenia wybranych chorób, ekonomia PM skupiła się głównie na ocenie skuteczności poszczególnych interwencji. Jednocześnie występuje brak kompleksowych ram teoretycznych do analizy zawiłych interakcji pomiędzy podmiotami farmaceutycznymi i systemami opieki zdrowotnej w zakresie operacjonalizacji personalizowanych metod leczenia. Ten brak konceptualizacji może potencjalnie utrudnić postęp PM w praktyce klinicznej [1].

Cele badania

Głównym celem cyklu prac była identyfikacja barier oraz czynników ułatwiających wdrażanie innowacyjnych interwencji oraz zidentyfikowanie najlepszych praktyk stosowanych w krajach europejskich, które wspierają wdrażanie nowatorskich interwencji z zakresu e-zdrowia, m-zdrowia i PM na poziomie mikro-, mezo- i makroregionalnym.

Cele szczegółowe to: określenie najlepszych praktyk w krajach europejskich wspierających implementację innowacyjnych interwencji w zakresie e-zdrowia, ocena istniejących barier oraz czynników ułatwiających wprowadzanie innowacyjnych interwencji medycznych w zakresie e-zdrowia, na podstawie dostępnego piśmiennictwa, przeprowadzenie badań jakościowych dotyczących wymiany najlepszych praktyk w zakresie implementacji

interwencji dotyczących e-zdrowia w ramach opieki (zdrowotnej i społecznej) i rozpowszechnianie wiedzy o wynikach badania.

Badania prowadzono i finansowano w ramach międzynarodowego projektu Regions4Permed (H2020) mającego na celu koordynację międzyregionalną na rzecz wymiany najlepszych praktyk w zakresie innowacyjnych interwencji dotyczących PM oraz ich implementacji w ramach opieki (zdrowotnej i społecznej), a także zwiększenie zaangażowania władz regionalnych, naukowców oraz decydentów we wdrażanie interwencji w tym zakresie.

Materiał i metody

Metodologia badania obejmowała badania desk research oraz badania jakościowe.

Wykorzystując metodę desk research, dokonano przeglądu dostępnej literatury dotyczącej barier i ułatwień w e-zdrowiu i m-zdrowiu opublikowanej w bazach Medline i Academic Search Ultimate, w okresie od stycznia 2015 do grudnia 2021, a następnie oceniano i interpretowano je zgodnie z zaleceniami PRISMA.

Następnie opracowano półstrukturalny kwestionariusz „Bariery i ułatwienia we wdrażaniu personalizowanej medycyny – badania jakościowe w ramach projektu Regions4PerMed (H2020)" oraz przeprowadzono trzy grupy fokusowe.

Wyniki

Spostrzeżenia na temat tego, co pomogłoby w adaptacji e-zdrowia, m-zdrowia i PM do potrzeb obywateli, zostały skategoryzowane na obszary potrzeb: edukacja; finanse; rozpowszechnianie; ochrona danych/IT/udostępnianie danych; analiza danych; zmiany systemowe/poziom rządowy; polityka zintegrowanej opieki; współpraca/współpraca; dostawcy usług medycznych; lekarze/praktycy; społeczeństwo/obywatele; zaangażowanie pacjentów.

Bariery i ułatwienia skategoryzowano wg kluczowych interesariuszy barier wdrożeniowych: rząd i agencje rządowe; lekarze/praktycy; system opieki zdrowotnej; świadczeniodawcy; pacjenci i organizacje pacjentów; sektor medyczny, środowisko naukowe, badacze, interesariusze; przemysł; twórcy technologii; instytucje finansowe; media.

Wnioski

Wdrożenie rozwiązań technologicznych prowadzi do usprawnienia procedur diagnostycznych i procesów decyzyjnych w opiece zdrowotnej oraz społecznej, co skutkuje lepiej dopasowanym skoordynowanym leczeniem, zmniejszeniem kosztów i skróceniem czasu

leczenia. E- zdrowie ułatwia diagnozowanie, zapobieganie i leczenie chorób i ostatecznie ma na celu przełamanie barier między podmiotami świadczącymi usługi zdrowotne, w tym agencjami rządowymi i szpitalami, aby umożliwić bliższą współpracę. Jednak e-zdrowie nadal stoi przed wyzwaniami, w tym: niespójnym prawodawstwem, biurokratycznymi procedurami i długimi procesami legislacyjnymi. Ponadto barierą we wdrażaniu PM jest sposób kształcenia lekarzy, zbyt mała świadomość dotycząca istnienia PM wśród społeczeństwa.

III. Abstract

Introduction

Personalised Medicine (PM), in which we also include e-health (electronic health) and m-health (mobile health), refers to treatment that is tailored to the patient's characteristics, needs and preferences. It categorises patients according to their risk of developing a particular disease or their level of response to a particular treatment using appropriate diagnostic markers. PM also aims to increase control over the optimisation of medical treatment outcomes and the precision of medical treatment, as well as to improve the prediction of disease.

A smart and organised approach is needed to ensure the quality and long-term viability of European healthcare systems and the integration of PM into clinical practise. This is crucial for shaping the future of health and social care in Europe.

The dynamic evolution of PM is becoming increasingly evident as individual characteristics have a greater impact on disease progression and drug efficacy. With PM, people are closer to more accurate, predictable and powerful health and social care that is tailored to the individual patient.

lthough PM has emerged as a novel approach to treating selected diseases, the economics of PM have focused predominantly on evaluating the effectiveness of specific interventions and have neglected a comprehensive theoretical framework for examining the intricate interplay between pharmaceutical companies and health systems in operationalising personalised treatments. This conceptual deficit has the potential to hinder the progress of PM in clinical practise [1].

Aims

The main aim of this study was to identify barriers and facilitators to the implementation of innovative interventions and to identify best practices applicable in European countries that support the implementation of cutting-edge e-health, m-health and PM interventions at the micro-, meso- and macro-regional levels.

The detailed objectives were to identify best practices in European countries that support the implementation of innovative e-health interventions, to identify existing barriers and facilitators to the implementation of innovative medical e-health interventions based on the available literature, to conduct a qualitative study on the exchange of best practices in the implementation of e-health interventions in (health and social) care, and to disseminate the results of the study.

The research was funded and conducted as part of the international Regions4PerMed project (H2020), which aims the interregional coordination for the exchange of best practices in innovative interventions related to PM and their implementation in health and social care, as well as increasing the engagement of regional authorities, researchers, and decision-makers in implementing interventions in this field.

Material and methods

The methodology of the study was desk research and qualitative research.

Using the desk research method, an analysis of existing articles was conducted. The available literature on barriers and facilitators in e-health and m-health published in Medline and Academic Search Ultimate databases from January 2015 to December 2021 was reviewed, evaluated and analysed according to PRISMA recommendations. The review is described in detail later in the thesis.

Subsequently, a semi-structured questionnaire "Barriers and facilitators of Personalised Medicine implementation-qualitative study under Regions4PerMed (H2020) project" and three focus groups were developed to address the topic of the study.

Results

The insights on what might be helpful in the adaptation of e-health, m-health and PM

to the citizen needs were categorised into the following areas of need: education; finance; dissemination; data protection/ IT /data sharing; data analysis; system changes/government level; integrated care policies; cooperation/collaboration; healthcare providers, physicians/practitioners; public/citizens; patient engagement.

Barriers and facilitators were categorised by key stakeholders of the implementation barriers: government and government agencies; physicians/practitioners; healthcare system; healthcare providers; patients and patient organisations; medical sector, scientific community, researchers, stakeholders; industry; technology developers; financial institutions; media.

Conclusions

The implementation of technological solutions leads to improved diagnostic procedures and decision-making processes in health and social care, resulting in better-tailored coordinated treatments, reduced costs and shorter treatment times. E-health facilitates the diagnosis, prevention and treatment of diseases and ultimately aims to break down barriers between healthcare providers, including government agencies and hospitals, to enable closer

cooperation. However, e-health still faces challenges, including inconsistent legislation, bureaucratic procedures and lengthy legislative processes. Additionally, the barrier to the PM implementation is the method of physician education and also the lack of awareness about the PM among the society.

IV. Wstęp

Medycyna personalizowana (PM – ang. *Personalised Medicine*), w skład której zalicza się e-zdrowie (elektroniczne usługi zdrowotne) i m-zdrowie (mobilne usługi zdrowotne), to odejście od "uniwersalnego" podejścia do leczenia i opieki nad pacjentami z konkretnym schorzeniem na rzecz takiego, które wykorzystuje nowe podejścia do lepszego zarządzania zdrowiem pacjentów i ukierunkowuje terapie w celu osiągnięcia najlepszych wyników w zarządzaniu chorobą lub predyspozycjami pacjenta do choroby. [2]

PM odpowiada na wyzwania związane z brakiem skuteczności powszechnie stosowanych leków w leczeniu dużej liczby pacjentów. Przyczynia się to do wzrostu kosztów opieki zdrowotnej z powodu większej liczby rozpowszechnionych chorób przewlekłych i starzejącej się populacji. PM to jednak strategie zapobiegania i leczenia dostosowane do potrzeb poszczególnych osób lub grup, dzięki czemu pacjenci otrzymują konkretne terapie, które będą dla nich najlepsze, a zasoby finansowe są wykorzystywane w sposób ukierunkowany. [3]

PM jest odwrotnością i uzupełnieniem współczesnej medycyny. Medycyna tradycyjna to odgórne, populacyjne podejście randomizowanych badań kontrolowanych (RCT - *Randomized controlled trial* i medycyny opartej na dowodach (EBM - *Evidence-Based Medicine*) [4 - 5].

PM jest podejściem oddolnym. Identyfikacja mechanizmów zaburzeń, zanim staną się one zaawansowaną, zdefiniowaną chorobą, jest potrzebna do celowanej, personalizowanej terapii. Podczas gdy wysokopoziomowe koncepcje stają się jasne, pozostaje wiele barier w zakresie informacji, integracji, tłumaczenia, logistyki i akceptacji, szczególnie w Europie Środkowej i Wschodniej, które będą musiały być rozwiązane przez przyszłe, dobrze zaprojektowane badania podstawowe i kliniczne. [6]

Dowody wskazują, że w większości przypadków PM nie jest omawiana w punkcie opieki. Ostatnie badanie publiczne wykazało, że tylko czterech na dziesięciu pacjentów jest świadomych istnienia PM, a tylko 11% pacjentów twierdzi, że ich lekarz omówił lub zalecił im opcje leczenia PM [7].

E-zdrowie i m-zdrowie stają się dyspozycyjnymi elementami opieki zdrowotnej i społecznej, obejmującymi szeroki zakres usług zdrowotnych, od elektronicznych recept i dokumentacji medycznej po komunikację z pacjentem w celu poprawy przestrzegania przez niego zaleceń [8]. Rynek e-zdrowia rozwija się bardzo dynamicznie. Według prognoz, jego wartość wzrośnie z 45 miliardów dolarów w 2020 roku do 194 miliardów dolarów w 2027 roku. W okresie prognozowanym na lata 2021-2027, przewidywany jest skumulowany roczny

wskaźnik wzrostu (ang. *Compound Annual Growth Rate* - CAGR) na poziomie 23% [9]. Jednak mimo rosnących inwestycji i zainteresowania e-zdrowiem, aby umożliwić szersze i bardziej systematyczne wdrażanie technologii informacyjno-komunikacyjnych w opiece zdrowotnej, należy jeszcze pokonać kilka wyzwań. Usługi i systemy opieki zdrowotnej i społecznej muszą stać się bardziej odporne, skuteczne, sprawiedliwe, dostępne, zrównoważone i kompleksowe. Transformacja i adaptacja wymagają zorientowanego cyfrowo sposobu myślenia [10].

Wraz z ewolucją coraz większej liczby e-usług, opieka zdrowotna świadczy wiele różnych usług e-zdrowia. Ogólnie rzecz biorąc, e-zdrowie wiąże się z pozytywnym wpływem na wyniki opieki zdrowotnej i społecznej. Poprawa efektywności kosztowej, więcej informacji o stanie zdrowia pacjenta i lepsza komunikacja między pracownikami służby zdrowia to tylko niektóre przykłady korzyści płynących z usług e-zdrowia. Często jednak usługi e-Zdrowia nie są przyjmowane i brakuje im akceptacji ze strony ich użytkowników. Dla wybranych usług, domen lub grup pacjentów, poziomy akceptacji i związane z nimi wskaźniki przyjęcia są zgłaszane jako wyższe [11]. Za tym opóźnieniem w adopcji klinicznej kryją się nowe wyzwania, które systemy opieki zdrowotnej i społecznej napotykają w trakcie dostosowywania się do nowych wymagań, praktyk i standardów związanych z tą dziedziną [12].

PM stoi przed wieloma wyzwaniami i barierami, które muszą zostać skutecznie wdrożone w systemach opieki zdrowotnej i społecznej. Należy jednak pamiętać, że PM nie jest rewolucją medyczną, lecz ewolucją. Koncepcja PM istnieje od kilkudziesięciu lat, a wykorzystanie podejścia personalizowanego w leczeniu systematycznie wzrasta. Rozwój nowych technologii przyspieszył rozwój PM w ostatnich latach. Jednak te postępy są zbudowane na fundamencie badań naukowych i praktyki medycznej, które sięgają wiele lat wstecz. W tym sensie PM może być postrzegana jako ewolucja praktyki medycznej, a nie nagła, rewolucyjna zmiana. Rozwój PM jest ciągłym procesem, który opiera się na istniejącej wiedzy i technologii i będzie nadal ewoluował wraz z odkryciami i rozwojem nowych technologii [13].

W niniejszym cyklu artykułów omówiono znaczenie oceny barier i ułatwień we wdrażaniu interwencji w zakresie e-zdrowia, m-zdrowia oraz PM.

V. Założenia i cel pracy

Głównym celem prac wchodzących w skład cyklu była identyfikacja barier oraz czynników ułatwiających wdrażanie innowacyjnych interwencji w zakresie e-zdrowia w pięciu obszarach strategicznych Projektu Regions4PerMed: Big Data w medycynie i elektroniczna dokumentacja medyczna; technologie medyczne w modelach zintegrowanej opieki zdrowotnej; przemysł medyczny; usprawnienia we wprowadzaniu innowacji w opiece zdrowotnej; aspekty społeczno – ekonomiczne w zakresie e-zdrowia.

Celami szczegółowymi były:

a) Określenie najlepszych praktyk stosowanych w krajach europejskich wspierających implementację innowacyjnych interwencji w zakresie e-zdrowia na poziomie mikro-, mezo- i makroregionalnym możliwych do zastosowania w ramach polskiego systemu opieki (zdrowotnej i społecznej) [14];
b) ocena istniejących barier oraz czynników ułatwiających wprowadzanie innowacyjnych interwencji medycznych w zakresie e-zdrowia, [14];
c) przeprowadzenie badań jakościowych dotyczących wymiany najlepszych praktyk w zakresie implementacji interwencji dotyczących e-zdrowia w ramach opieki (zdrowotnej i społecznej) [13, 15];
d) Rozpowszechnianie wiedzy o wynikach badania na poziomie mikro-, mezo- i makroregionalnym [13-15].

VI. Materiały i metody badań

Rozprawa doktorska powstała jako rezultat międzynarodowego projektu *Regions4PerMed - Interregional coordination for a fast and deep uptake of personalised health* finansowanego w ramach programu Komisji Europejskiej Horyzont 2020, który realizowany był w latach 2018-2023. Trzonem konsorcjum projektu były urzędy jednostek samorządów terytorialnych i współpracujące z nimi agencje rozwoju regionalnego pięciu regionów: Lombardii - *Fondazione Regionale per la Ricerca* Biomedica, Toskanii - *Tuscany Life Sciences*, Saksonii - *Sächsisches Staatsministerium für Wissenschaft und Kunst*, Galicji - *Axencia de Coñecemento en Saúde* i Dolnego Śląska - Urząd Marszałkowski Województwa Dolnośląskiego. Uniwersytet Medyczny we Wrocławiu był jedynym ośrodkiem akademickim w ramach konsorcjum. Głównym celem projektu "Interregional Coordination for a Fast and Deep Uptake of Personalised Health" (Regions4PerMed) było zwiększenie zaangażowania odpowiednich interesariuszy, czyli władz regionalnych, naukowców, decydentów i organizacji klastrowych, w wdrażanie PM. Innym kluczowym celem było ustanowienie pierwszej międzyregionalnej współpracy w zakresie PM, dostosowanie strategii i instrumentów finansowych, identyfikacja kluczowych obszarów inwestycyjnych oraz opracowanie europejskiej agendy regionalnej w celu wsparcia świadczenia usług w zakresie PM dla pacjentów i obywateli [16].

W celu oceny istniejących barier oraz czynników ułatwiających wprowadzanie innowacyjnych interwencji medycznych w zakresie e-zdrowia przeprowadzono, jako pierwszą, analizę istniejących artykułów. Wykorzystując metodę badawczą desk research, dokonano przeglądu opublikowanych materiałów, dostępnej literatury oraz dokumentów za pomocą baz online. Przegląd systematyczny objął dokumenty dotyczące barier i ułatwień w stosowaniu e-zdrowia i m-zdrowia, opublikowane w bazie Medline i Academic Search Ultimate, w okresie od stycznia 2015 do grudnia 2021 roku. Publikacje zostały ocenione i zinterpretowane zgodnie z zaleceniami PRISMA.

Zidentyfikowano 5337 rekordów przy użyciu Medline i Academic Search Ultimate. Słowa kluczowe używane w całym procesie badawczym to: *m-health; e-health; barriers; facilitators; challenges; chronic diseases*. Artykuły spełniały kryteria, jeśli były opublikowane w recenzowanych czasopismach akademickich, napisane w języku angielskim i dostępny był ich pełny tekst. Po odrzuceniu artykułów nie spełniających ww. kryteriów pozostały 1504 rekordy. 1187 zostało wykluczonych po ocenie tytułu i abstraktu, a 297 zostało wykluczonych po analizie pełnego tekstu. Analizie poddano pozostałe 22 badania.

Ponadto omówiono wyniki konferencji *Health Technology in Connected & Integrated Care*, która odbyła się w ramach projektu Horyzont 2020 „*Interregional coordination for a fast and deep uptake of personalised health*" (Regions4Permed) w lipcu 2020 r. Podczas konferencji wystąpiło 16 prelegentów, przeprowadzono 3 wizyty studyjne. W konferencji wzięło udział 86 zarejestrowanych uczestników, a średni czas przebywania na sali wyniósł 170,5 min. Uczestnikami konferencji byli eksperci ze środowiska akademickiego i przemysłu oraz przedstawiciele regionalnych i rządowych instytucji polityki zdrowotnej z różnych krajów UE. Liczba uczestników konferencji wynosiła: 86 zarejestrowanych uczestników i 19 prelegentów z 17 krajów. Podsumowano również istniejące w Europie rozwiązania w zakresie PM, opierając się na broszurach Best Practice opracowanych w ramach projektu Regions4PerMed.

Półstrukturalną ankietę "*Barriers and facilitators of Personalised Medicine implementation-qualitative study under Regions4PerMed (H2020) project*" opracowano aby zrealizować kolejny cel szczegółowy. W tym etapie wzięło udział 85 respondentów, a odpowiedzi na ww. ankietę uzyskano w okresie od lipca 2020 do listopada 2022 r. Dane przekazywano przez kwestionariusz online (Google Forms). Respondentami byli Interesariusze projektu Regions4PerMed, do których należą członkowie Rady Doradczej projektu Regions4PerMed, wykładowcy na konferencjach i warsztatach oraz uczestnicy tych wydarzeń.

Wiek respondentów mieścił się w przedziale 24-74 lata. Wśród ankietowanych znajdują się badacze (naukowcy), przedsiębiorcy, doradcy polityczni, menedżerowie projektów, lekarze, urzędnicy, prawnicy, eksperci w dziedzinie zdrowia publicznego, menedżerowie opieki zdrowotnej, biostatystycy, konsultanci opieki zdrowotnej itp.

Respondenci pochodzili z 20 krajów, w tym z Ukrainy (UA), Włoch (IT), Niemiec (DE), Hiszpanii (ES), Polski (PL), Danii (DK), Belgii (BE), Wielkiej Brytanii (GB), Łotwy (LV), Kanady (CA), Estonii (EE), Turcji (TR), Rumunii (RO), Europy (EU), Francji (FR), Litwy (LT), Szwecji (SE), Grecji (GR), Holandii (NL), Portugalii (PT) i Kazachstanu (KZ). Odpowiedzi na ankiety zostały zakodowane w następującym formacie - symbol kraju i numer wskazujący na kolejność dostarczenia ankiet.

Przeprowadzono również, z wykorzystaniem platformy ZOOM, trzy grupy fokusowe dotyczące barier i ułatwień we wdrażaniu PM. W spotkaniach uczestniczyły trzy kategorie uczestników: obserwator, moderator i respondent. Pierwsza grupa fokusowa została przeprowadzona 10 listopada 2022 r. Jej uczestnikami byli przedstawiciele polskich instytucji rządowych, instytucji finansowych, przedstawicielami praw pacjentów oraz fundacji

pacjentów. W grupie tej uczestniczyło 7 osób, nie licząc obserwatora i moderatora. Druga grupa, która odbyła się 29 listopada 2022 roku składała się z przedstawicieli Komisji Europejskiej, włoskiego Ministerstwa Zdrowia, pofesora/ lekarza ogólnego z Ukrainy. W drugiej grupie fokusowej wzięły udział 4 osoby. Trzecia grupa odbyła się w dniu 12 grudnia 2022 roku. Jej uczestnikami byli przedstawiciele Saksońskiego Ministerstwa Nauki, Kultury i Turystyki oraz Fondazione Regionale per la Ricerca Biomedica. W spotkaniu tym uczestniczyły 3 osoby. Czas trwania jednej grupy - od 60 do 90 min. Dane gromadzono lokalnie na serwerze. Podczas każdej z grup zadawano pytania dotyczące indywidualnego rozumienia PM, kluczowych ułatwień i barier w publicznym wykorzystaniu PM oraz prywatnych opinii respondentów na temat łatwości dostosowania PM do potrzeb obywateli [13].

VII. Podsumowanie wyników

W fazie pierwszej badań (**Stefanicka-Wojtas, D.**; Kurpas, D. eHealth and mHealth in Chronic Diseases—Identification of Barriers, Existing Solutions, and Promoters Based on a Survey of EU Stakeholders Involved in Regions4PerMed (H2020). *J. Pers. Med.* **2022**, 12, 467. https://doi.org/10.3390/jpm12030467) przedstawiono wyniki osiągnięte za pomocą badań reaserch desk, w których wskazano bariery i czynniki ułatwiające wdrażanie e-zdrowia i m-zdrowia w chorobach przewlekłych, podzielone na czynniki indywidualne, technologiczne oraz polityczne/prawne. W artykule przybliżono też istniejące w Europie rozwiązania w zakresie PM, opierając się na broszurach Best Practice opracowanych w ramach projektu Regions4PerMed. Dane te zostały syntetycznie przedstawione w tabeli. Wskazano również, w formie tabelarycznej, na oczekiwane bariery i ułatwienia w osiągnięciu czterech celów:

a) poprawy indywidualnych doświadczeń związanych opieką zdrowotną,
b) poprawy stanu zdrowia populacji,
c) zmniejszenia kosztów opieki zdrowotnej na mieszkańca,
d) poprawy doświadczeń związanych z zapewnieniem opieki (znaczenie lekarzy, pielęgniarek etc).

W dalszym etapie badań (Stefanicka-Wojtas, D.; Kurpas, D. Barriers and Facilitators to the Implementation of Personalised Medicine across Europe. J. Pers. Med. 2023, 13, 2023. https://doi.org/10.3390/jpm13020203), w którym przeprowadzono półstrukturalną ankietę "Barriers and facilitators of Personalised Medicine implementation" wyniki zostały przedstawione w postaci wykresów, przedstawiających podział na stopień świadomości społecznej w zakresie PM w ujęciu ogólnym oraz według narodowości respondentów. Przedstawiono również porównanie świadomości społecznej w zakresie PM w zależności od dochodów danego kraju oraz jego PKB per capita. Dodatkowo dokonano tabelarycznej analizy odpowiedzi udzielonych na szczegółowe pytania dotyczące osobistej opinii respondentów na temat istniejących barier i ułatwień we wdrażaniu PM. Odpowiedzi zostały pogrupowane według kluczowych interesariuszy, którzy są zaangażowani w przezwyciężanie barier wdrożeniowych tj.: rząd i agencje rządowe, lekarze/praktycy medyczny, systemy opieki zdrowotnej, dostawcy usług medycznych, pacjenci i organizacje pacjenckie, sektor medyczny/społeczność naukowa/ badacze, przemysł, twórcy technologii, instytucje finansowe, media. Dzięki takiemu podejściu możliwe było przeprowadzenie kompleksowej

analizy wyników badania i uzyskanie bardziej szczegółowego obrazu społecznej świadomości w zakresie PM [15].

W celu osiągnięcia pełniejszych danych jakościowych dotyczących wymiany najlepszych praktyk w zakresie implementacji interwencji dotyczących PM przeprowadzone zostały grupy fokusowe (Stefanicka-Wojtas, D.; Kurpas, D. Personalised Medicine—Implementation to the Healthcare System in Europe (Focus Group Discussions). J. Pers. Med. 2023, 13, 380. https://doi.org/10.3390/jpm13030380). Wygenerowały one dane empiryczne na temat indywidualnych doświadczeń respondentów w odniesieniu do barier i ułatwień we wdrażaniu PM w całej Europie. Wyniki uzyskane w ramach tego etapu badań zostały podzielone na obszary tematyczne, w tym zagadnienia związane z ochroną i analizą danych, systemami rządowymi, dostawcami usług medycznych, instytucjami finansowymi, danymi dotyczącymi lekarzy i praktyków medycznych, systemami opieki zdrowotnej, pacjentami oraz rozwojem technologii [13].

Poniżej przedstawiono wyniki ze spójnych tematycznie badań ankietowych i grup fokusowych:

Definicja PM

W trakcie grup fokusowych uwidoczniły się przede wszystkim różnice w definiowaniu PM. Jedna z definicji opisuje PM jako medycynę zindywidualizowaną opartą na badaniach genetycznych i dopasowanych interwencjach zdrowotnych, zarówno w medycynie prewencyjnej, jak i naprawczej, czyli dopasowanie najlepszej dla danej osoby terapii na podstawie określonych predyspozycji genetycznych. Kolejna z nich to definicja opublikowana w Konkluzjach Rady Europejskiej w grudniu 2015 roku. Według innego podejścia PM istnieje w momencie, gdy opieka uwzględnia osobiste czynniki ryzyka i choroby współistniejące oraz decyduje, co najlepiej przepisać pacjentom w zależności od ich sytuacji, statusu ekonomicznego itp. Kolejne rozumienie PM opiera się na tezie, że lekarze i pielęgniarki w każdej placówce medycznej posiadają informacje o pacjentach, takie jak ich wiek, wcześniejsze choroby lub stany chorobowe, informacje o alergiach itp. i na podstawie tych informacji stawiana jest diagnoza.

Systemy gromadzenia danych medycznych/ przetwarzanie danych / ochrona danych

Główne rozpoznane do tej pory problemy z zakresu danych medycznych dotyczyły ochrony danych, ich integracji, porównywalności, wymiany danych zarówno w obrębie kraju jak i pomiędzy krajami. Podczas grup fokusowych zauważono jednak dodatkowy problem. Personalizowane terapie celowane są często stosowane w małych grupach i małych populacjach pacjentów w bardzo specyficznych sytuacjach, co w konsekwencji stwarza wiele

trudności w uzyskaniu wiarygodnych, zwalidowanych danych. Nie ma możliwości naukowej walidacji oceny skuteczności takiej terapii, która może trwać latami w "nienaukowych" warunkach dla celów komercyjnych, często ze szkodą dla pacjentów.

Rząd/systemy polityczne/ Świadczeniodawcy opieki zdrowotnej

W europejskich systemach opieki zdrowotnej istnieje niespójne ustawodawstwo, a współpraca z agencjami rządowymi oznacza niestety biurokrację i długie procedury legislacyjne [14]. Polityka i programy w zakresie PM również znacznie się różnią [17]. Świadczeniodawcy opieki zdrowotnej mają przed sobą długą drogę do pełnego wykorzystania potencjału PM. Wysiłki mające na celu integrację nowych technologii i praktyk PM są nadal we wczesnym stadium, a świadczeniodawcy opieki zdrowotnej stoją przed wieloma wyzwaniami.[18].

Dane pozyskane z grup fokusowych wskazały ułatwienie, które musi być wykorzystywane na dużą skalę. Aby wskazać decydentom drogę, która pozwoli przełożyć e-zdrowie, m-zdrowie czy całą PM na zarządzanie opieką zdrowotną i społeczną konieczne jest posiadanie, wskazywanie i rozpowszechnianie wiedzy dotyczącej przykładów dobrych praktyk wdrożonych już w innych krajach. Najważniejszym czynnikiem wprowadzenia PM do systemu opieki zdrowotnej są bowiem dowody. Istnieje potrzeba wykazania dowodów na istnienie PM oraz zasadności jej celów. Jest to najważniejsza kwestia dla naukowców, klinicystów i decydentów. Istnieje również wyraźna potrzeba większej liczby badań klinicznych. Zdaniem respondentów należy również przeprowadzić reformę systemu opieki zdrowotnej, zmienić podejście systemowe i dialog z podmiotami publicznymi oraz agencjami HTA (ang. *health technology assessment*), a także zmienić sposób zarządzania poprzez odpowiednie zachęty finansowe. Dodatkowo jedną z propozycji wynikających z badań jest wprowadzenie tzw. case managerów lub towarzyszy pacjenta, czyli osób, które wspierają pacjentów w systemie, szczególnie w przypadku bardzo groźnych chorób. Wraz z pogłębianiem się personalizacji w opiece zdrowotnej pojawia się bowiem potrzeba doradztwa dla pacjentów.

Instytucje finansowe

PM może przyczynić się do poprawy wyników opieki zdrowotnej, jak również do oszczędności kosztów, głównie poprzez wyeliminowanie podawania niektórych leków pacjentom, co do których przewiduje się, że nie będą na nie reagować. Niektóre z terapii personalizowanych mogą jednak zwiększać koszty terapii. Dlatego też wdrożenie PM wymaga jednocześnie od decydentów zdrowotnych oceny potencjalnej wartości personalizowanej terapii w porównaniu ze standardowym leczeniem dla każdego indywidualnego wskazania

i kontekstu medycznego, ponieważ korzyści zdrowotne PM bardzo często wymagają również wyższych budżetów zdrowotnych [1].

W ankietach oraz grupach fokusowych został zauważony jednak dodatkowy, istotny problem. Finansowanie terapii ze świadczeniami gwarantowanymi lub leków refundowanych przez rząd jest jednak problematyczne, ponieważ grupy pacjentów, do których skierowane są te terapie, są często bardzo małe. Takie zawężenie grup pacjentów często prowadzi do nadawania lekom statusu leków sierocych, co skutkuje bardzo wysokimi cenami tych leków i terapii, trudnymi do udźwignięcia przez system refundacyjny. Dodatkowo, jak podkreślano wielokrotnie, należy opracować finansowanie/ramy dla podtrzymania udanych projektów (te często są przerywane po początkowym okresie finansowania).

Lekarze/praktycy medyczni

Dużą barierą zauważoną w trakcie badań jest sposób, w jaki kształci się dziś lekarzy. Są oni bardzo skoncentrowani na konkretnych obszarach chorobowych i brakuje im świadomości innych dyscyplin, co sprawia, że pełne przyjęcie PM wymaga kompleksowego podejścia medycznego. W związku z tym zmiany w szkoleniu lekarzy, jeśli zostanie przyjęte, holistyczne podejście lekarza do pacjenta może być ważnym czynnikiem ułatwiającym wdrażanie PM.

Pacjenci

Poza zmianą sposobu kształcenia medyków ważne jest aby społeczeństwo stało się świadome istnienia PM oraz najlepszych praktyk, które mogłyby ją stworzyć. Należy też oswajać pacjentów w sprawie e-usług i zapewniać o bezpieczeństwie ich danych w sieci. Istnieje coraz więcej dowodów na to, że lepiej poinformowani pacjenci poprawiają samoopiekę i przestrzeganie leków oraz poprawiają swoje zdrowie i samopoczucie. Zdolność obywateli do dostępu do danych równiej jest uważana za ważną ze względu na poprawę zarządzania chorobą jako nową formą zaangażowania i wzmocnienia pozycji pacjenta [19].

Rozpowszechnianie informacji

Pomijanym bardzo często tematem, w dostępnej literaturze, jest rozpowszechnianie wiedzy o PM. W badaniach przeprowadzonych przez doktoranta podkreślane jest bardzo duże znaczenie lepszego rozpowszechniania wiedzy o PM, udostępniania informacji w mediach w ramach mediów społecznościowych, poprawienie jakości reklam w telewizji i mediach społecznościowych oraz organizowania spotkań ze wszystkimi interesariuszami, w tym z pacjentami. Ważne jest szersze rozpowszechnianie wyników badań naukowych wśród pacjentów i obywateli.

VIII. Ograniczenia badania

Podczas analizy istniejących artykułów wyszukiwanie było ograniczone do artykułów opublikowanych w języku angielskim. Wykluczenie artykułów napisanych w innych językach mogło ograniczyć dostęp do badań o znaczących wynikach związanych z celem pracy. Warto jednak podkreślić, że z tego powodu korzystano z więcej niż jednej bazy publikacji tj. PubMed/MEDLINE i Academic Search Ultimatewere.

Badania opierają się na małej liczebności próby jednak mogą dostarczać uogólnionych wyników na poziomie kraju. Kwestionariusze zostały wysłane do różnych interesariuszy projektu Regions4PerMed. Profil zawodowy respondentów jest zróżnicowany - od naukowców (badaczy), przedsiębiorców, personelu naukowego, polityków, doradców politycznych, menedżerów projektów, po lekarzy, urzędników, prawników, ekspertów ds. zdrowia publicznego, menedżerów ds. zdrowia publicznego, biostatystyków, konsultantów ds. zdrowia publicznego itp. Różnorodność wiekowa respondentów jest również zauważalna, dzięki czemu można uzyskać przegląd barier i ułatwień w wdrożeniu PM z różnych perspektyw wiekowych.

W grupach fokusowych jednym z ograniczeniem jest możliwość generalizowania lub kategoryzowania przez moderatorów indywidualnych opinii. Aby temu zapobiec, oprócz moderatora, w grupach fokusowych uczestniczył również obserwator. Ponadto, osoby o silnym wpływie, takie jak moderatorzy i aktywni członkowie grupy, mogą wpływać na rozmowę, tłumić opinie mniej aktywnych uczestników. Aby uniknąć tego ograniczenia, moderator grup starał się prowadzić rozmowę w taki sposób, aby każdy uczestnik mógł wyrazić swoją opinię.

Zarówno w badaniach ankietowych jak i przeprowadzonych grupach fokusowych za ograniczenie badania można uznać również treść kwestionariusza lub pytania zadawane podczas spotkań. Treść pytań jednak została zatwierdzona przez współbadacza z doświadczeniem w badaniach jakościowych i ilościowych.

IX. Rekomendacje i proponowane kierunki dalszych badań

Rekomendacje:

1. Priorytetowo powinna zostać potraktowana współpraca międzyregionalna pomiędzy różnymi krajami europejskimi w celu ujednolicenia obowiązujących w danych krajach legislacji dotyczących głównie wymiany danych medycznych np. danych genomowych.
2. Regiony, jako jednostki administracyjne bliższe potrzebom danego terytorium, powinny angażować wszystkie zainteresowane podmioty w kształtowanie nowej polityki w zakresie e-zdrowia i m-zdrowia.
3. Powinny zostać wdrożone na szerszą skale systemy informatyczne, które będą przechowywać i udostępniać dane pacjentów. Systemy opieki zdrowotnej i społecznej muszą być bowiem zdolne do gromadzenia i analizowania danych dotyczących zdrowia pacjenta. Ważne jest, aby wykorzystywać narzędzia, które są najlepiej dostosowane do konkretnych celów badawczych.
4. Należy zapewnić odpowiednie zabezpieczenia technologiczne oraz przestrzegać rygorystycznych standardów dotyczących prywatności danych.
5. Ważne jest holistyczne podejście do pacjenta. PM powinna uwzględniać, poza wynikami badań, styl życia, środowisko, wiek i inne czynniki, które mają wpływ na zdrowie pacjenta.
6. Pacjenci powinni być zaangażowani w proces personalizowanej opieki medycznej i powinni być poinformowani o korzyściach i ograniczeniach tej formy leczenia. Ważne jest, aby pacjenci zrozumieli, że personalizacja medycyny to proces, a nie jednorazowe rozwiązanie.
7. Kadra medyczna powinna doskonalić swoje umiejętności i wiedzę, aby zapewnić najlepsze wyniki dla pacjentów.
8. Personalizowana medycyna, w tym e – zdrowie i m – zdrowie, powinny być dostępne dla jak największej liczby pacjentów.
9. Pacjenci powinni mieć dostęp do informacji na temat personalizowanej medycyny, aby móc podjąć informowane decyzje dotyczące swojego zdrowia.
10. Intensyfikacja inwestycji w badania naukowe, dzięki którym zostaną opracowane skuteczniejsze i bardziej opłacalne terapie personalizowane.

Proponowane kierunki dalszych badań w dziedzinie medycyny personalizowanej, w tym e-zdrowiu i m-zdrowiu:

1. Badanie wpływu PM, e-zdrowia i m-zdrowia na redukcję kosztów służby zdrowia poprzez bardziej skuteczne i celowane leczenie chorób.
2. Badania wpływu działań prewencyjnych stosowanych w ramach PM, e-zdrowia i m-zdrowia na zapobieganie chorobom i zmniejszenie kosztów opieki zdrowotnej.
3. Praca nad ulepszeniem interakcji między pacjentami a lekarzami poprzez zastosowanie nowych technologii – e-zdrowia i m-zdrowia.
4. Badania nad wprowadzeniem bardziej zaawansowanych narzędzi analizy danych, które pomogą w personalizacji opieki zdrowotnej i społecznej.
5. Badanie wpływu e-zdrowia i m-zdrowia na jakość życia pacjentów i pracowników służby zdrowia.
6. Projektowanie i rozwijanie interaktywnych narzędzi do samodzielnego monitorowania zdrowia.
7. Badania nad wdrażaniem nowych modeli biznesowych, tak aby firmy ubezpieczeniowe, dostawcy opieki zdrowotnej i pacjenci mieli większą możliwość oferowania i korzystania do korzystania z PM.
8. Badania nad normami bezpieczeństwa i prywatności w ramach e-zdrowia, m-zdrowia i PM zapewniające pacjentom bezpieczeństwo i ochronę danych medycznych.
9. Badanie skuteczności interwencji mobilnych (m-zdrowia, e-zdrowia), w celu poprawy zdrowia psychicznego i fizycznego pacjentów.
10. Badania nad rozwijaniem technologii e-zdrowia i m-zdrowia, takich jak aplikacje mobilne i platformy internetowe, które umożliwiają zdalny monitoring stanu zdrowia pacjenta, dzięki czemu pacjenci mogą być lepiej kontrolowani i opiekowani, oraz które umożliwią szybką reakcję na pogorszenie stanu zdrowia pacjenta.

X. Wnioski

W niniejszej rozprawie zidentyfikowano bariery i czynniki ułatwiające wprowadzenie interwencji w zakresie e-zdrowia, które muszą być skutecznie zarządzane w europejskich systemach opieki zdrowotnej i społecznej [13-15]. Elektroniczne usługi medyczne (e-zdrowie) i mobilne usługi medyczne (m-zdrowie) są teraz niezbędnymi elementami opieki zdrowotnej [7]. Jednakże, jak wynika z analiz i badań jakościowych przeprowadzonych w artykułach poruszanych w rozprawie, istnieje wiele barier, które hamują wdrażanie e-zdrowia, m-zdrowia i PM w całej Europie. Mimo wymiernych korzyści, skomplikowany proces adaptacji PM do krajów członkowskich UE i europejskich systemów opieki zdrowotnej i społecznej opóźnia jej powszechne przyjęcie.

Technologiczne rozwiązania mają pozytywny wpływ na usprawnienie procedur diagnostycznych i procesów decyzyjnych w opiece zdrowotnej i społecznej. Wdrożenie e-zdrowia i m-zdrowia pozwala na bardziej personalizowane i skoordynowane leczenie, co prowadzi do zmniejszenia kosztów i skrócenia czasu leczenia. Wszystko to przyczynia się do przełamania barier między różnymi podmiotami świadczącymi usługi zdrowotne, takimi jak agencje rządowe i szpitale, co z kolei umożliwia bliższą współpracę. Technologie medyczne są kluczowe w profilaktyce, diagnostyce, leczeniu i rehabilitacji pacjentów, zarówno w opiece domowej, jak i ambulatoryjnej oraz na oddziałach szpitalnych. Poprawiają one efektywność opieki zdrowotnej i skracają czas oraz koszty leczenia. Jednak wraz z wprowadzeniem nowych technologii ważne jest, aby ludzie zwiększali swoje kompetencje w zakresie korzystania z nich. Mimo że e-zdrowie przynosi wiele korzyści, nadal stoi przed wyzwaniami, takimi jak niespójne prawodawstwo, biurokratyczne procedury i długie procesy legislacyjne. Kolejną barierą w wdrożeniu PM jest sposób kształcenia lekarzy oraz niska świadomość dotycząca istnienia PM wśród społeczeństwa [14].

Aby skutecznie zastosować PM w systemach opieki zdrowotnej i społecznej, należy rozwiązać wiele istotnych wyzwań. Należą do nich integracja dużych, zmiennych i różnorodnych zbiorów danych (*Big Data*), zwiększenie świadomości zdrowotnej, uregulowanie kwestii refundacji oraz regulacyjnych. Rozwiązanie tych problemów pozwoli na poprawę dokładności diagnostyki, co umożliwi identyfikację najlepszej opcji leczenia dla danego pacjenta na podstawie jego indywidualnych cech. Ukierunkowana terapia zmniejsza efekty uboczne, pozwala na lepsze zapobieganie chorobom i zwiększa zaangażowanie pacjentów. Ponadto, zastosowanie medycyny personalizowanej może pomóc w zmniejszeniu kosztów opieki zdrowotnej i promować badania i innowacje [13-15]. Warto

jednak podkreślić, że medycyna personalizowana jest wynikiem ewolucji praktyki medycznej, a nie nagłej, rewolucyjnej zmiany. Koncepcja PM istnieje od wielu lat, a zastosowanie podejścia personalizowanego w leczeniu stale się rozwija. Postępy te są wynikiem badań naukowych i praktyki medycznej, które sięgają wielu lat wstecz. Dlatego ważne jest, aby wdrożenie PM opierało się na solidnym fundamencie naukowym i były stopniowe, uwzględniające postęp technologiczny i wyniki badań naukowych [13].

XI. Piśmiennictwo

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XII. Publikacje wchodzące w skład rozprawy doktorskiej

Oświadczenia współautorów prac określające indywidualny wkład każdego z nich zawiera załącznik nr 2.

Journal of *Personalized Medicine*

MDPI

Article

eHealth and mHealth in Chronic Diseases—Identification of Barriers, Existing Solutions, and Promoters Based on a Survey of EU Stakeholders Involved in Regions4PerMed (H2020)

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Abstract: Background: In recent years, rapid population ageing has become a worldwide phenomenon. Both electronic health services (eHealth) and mobile health services (mHealth) are becoming important components of healthcare delivery. The market for mHealth is growing extremely fast. However, despite the increasing investment and interest in eHealth, several challenges still need to be overcome to enable broader and more systematic implementation of ICT in healthcare. Methods: This study presents data from the survey "Barriers and facilitators of Personalised Medicine implementation- qualitative study under Regions4PerMed (H2020) project". In addition, this paper discusses the results of the conference, Health Technology in Connected & Integrated Care, held under the Horizon 2020 project and interregional coordination for a fast and deep uptake of personalised health (Regions4Permed) (July 2020—online conference). The above sections were preceded by an analysis of existing articles. Results: The data obtained from the surveys show that the main barriers to the adoption of eHealth and mHealth are the lack of skills of seniors, but also the lack of user-friendly technology and a simple user interface. Access to individual data while ensuring its security and the lack of digitisation of medical data are also serious issues. In addition, medical digital solutions are overly fragmented due to national legislations that deviate from the General Data Protection Regulation. Conclusions: By using technological solutions, it is possible to improve diagnosis and treatment decisions, and better adapt treatment and reduce its duration and cost. However, there are still barriers to the development of eHealth. Clear recommendations for implementation are needed to enable further development of personalised eHealth and mHealth solutions

Keywords: mHealth; eHealth; chronic diseases; interregional cooperation; barriers; facilitators; healthcare systems

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1. Introduction

Electronic health (eHealth) and mobile health (mHealth) services are becoming indispensable components of healthcare, covering a wide range of health services, from electronic prescriptions and medical records to patient communications to improve patient compliance [1].

The future of European healthcare systems and the implementation of personalised medicine in clinical practice require smart planning and a structured approach to ensure quality and long-term sustainability.

To this end, attention should be focused, in particular, on technologies and ICT that can deliver the desired outcomes for reorienting personalised and patient-centred healthcare systems.

Quality of care must be the focus of attention for politicians and decision-makers in all regions of Europe. Health services need to prioritise people with multiple chronic conditions (comorbidity), and it seems that this can be achieved through an integrated

and patient-centred approach that allows the needs of patients to be adequately met [2]. The authors, e.g., Talboom—Kamp et al. (2016), emphasise that the pressure to implement self-management through eHealth is immense. The reason for this is the number of people with chronic diseases and comorbidity, which is rapidly increasing due to rapid ageing and higher life expectancy of the population [3].

The eHealth market is growing extremely rapidly and is expected to increase from $45 billion in 2020 to $194 billion in 2027, with a CAGR of 23% in the forecast year from 2021 to 2027 [4]. However, despite the growing investment and interest in eHealth, several challenges still need to be overcome to enable a broader and more systematic implementation of ICT in healthcare. Healthcare services and systems must become more resilient, effective, equitable, accessible, sustainable, and comprehensive. Transformation and adaptation require a digitally oriented mindset [3]. Foster and Sethares (2014) point out that the use of telehealth by older people will increase, but that effective adoption of such interventions can only be successful if the patient's perspective is at the forefront [5].

Pilot projects (including the one presented below) are being conducted around the world, and areas of opportunity are being identified that could potentially have global impact. Barriers to large-scale implementation such as standards, security, and interoperability are also being identified [6]. As Kampmeijer et al. (2016) noted, the successful use of eHealth/mHealth tools in health promotion programs for older people is highly dependent on the motivation and support they receive in using eHealth and mHealth tools [7]. It is also worth noting that according to Alwashmi et al. (2019), mHealth could increase patient autonomy by stimulating patient empowerment and motivation [8].

2. Purpose of the Study

The purpose of this paper is to identify the main barriers, facilitators, and interventions related to eHealth and mHealth services in chronic diseases, and to present the state of implementation of eHealth and mHealth services in daily practice by describing the research findings and existing gaps.

3. Materials and Methods

3.1. Study Design

This study presents data from the survey, "Barriers and facilitators of Personalised Medicine implementation- qualitative study under Regions4PerMed (H2020) project". The survey included: general information on gender and nationality, two questions on individual experiences with barriers and facilitators of personalised medicine implementation, and five questions about the implementation of personalised medicine itself. The qualitative study—survey research—is in progress. This article shows only results that are relevant to the goal of the study.

In addition, this paper discusses the results of the conference, Health Technology in Connected & Integrated Care, held as part of the Horizon 2020 project and interregional coordination for a fast and deep uptake of personalised health (Regions4Permed) (July 2020—online conference). The conference explored the impact of new regulations and what solutions can be adopted at the regional level:

- Training for healthcare professionals: health technologies are often beneficial to patients, but health professionals often encounter difficulties in using the equipment associated with these technologies, which can increase the risk of accidents;
- Patient engagement: there is growing evidence that increased patient awareness leads to better care and treatment adherence, as well as improved health and well-being;
- Economic impact of health technologies: critical to the market access of health technologies and the implementation of personalised medicine is the valuation of health technologies, which needs to be discussed to assess market barriers and identify potential solutions [2].

The above sections were preceded by an analysis of existing articles. Using the desk research method, it was possible to extract them in the form of published materials,

online databases, available literature, and documents. Systematic reviews of barriers and facilitators of eHealth and mHealth published in Medline and Academic Search Ultimate, between January 2015 and December 2021, were evaluated and interpreted according to PRISMA recommendations. The following keywords were used throughout the research process: mHealth, eHealth, barriers, facilitators, challenges, chronic diseases.

3.2. Setting

The article is based on the results of online surveys and the summary of the two-day conference, Health Technology in Connected & Integrated Care, held in July 2020 (online). Three sessions and one on-site day were held during the conference.

3.3. Participants

Survey: The 69 online surveys from 19 countries (Lithuania, Germany, Italy, France, Kazakhstan, Poland, Spain, Netherlands, Denmark, Portugal, Turkey, Latvia, Greece, Canada, Ukraine, Belgium, Estonia, Romania, and Sweden) were conducted. The participants of the survey included 33 women and 36 men, aged 24–74 years. The participants are experts in the field of eHealth, mobile health services, and personalised medicine. They are associated with research institutes, private founders, and local and national governments.

The questionnaires were sent to the stakeholders of the Regions4PerMed (interregional coordination for a fast and deep uptake of personalised health) project: presenters at conferences and workshops, and participants in these events. This methodology allows for analysis of experiences related to barriers and facilitators to implementation based on evidence from existing implementations of innovative eHealth interventions at micro-, meso-, and macro-regional levels within health and social care systems, particularly related to chronic disease management.

At the Health Technology in Connected & Integrated Care conference, 16 speakers, and 3 site visits were conducted. The conference was attended by 86 registered participants, and the average time spent in the room was 170.5 min.

3.4. Data Sources

This study represents an analysis of data obtained from existing articles [7–28], online surveys (data from the survey "Barriers and facilitators of personalised medicine implementation- qualitative study under Regions4PerMed (H2020) project", author of the survey Dorota Stefanicka—Wojtas), and results of the Health Technology in Connected & Integrated Care conference [2].

3.5. Study Size

Between July 2020 and January 2022, 69 surveys were conducted. The study used a series of structured questions in an online questionnaire (using Google Forms). Data were collected, stored in a database, and included in the study. Conference participants were experts from academia and industry, and representatives of regional and governmental health policy institutions from a variety of EU countries. The number of conference participants was: 86 registered participants and 19 speakers from 17 countries

3.6. Variables

3.6.1. Quantitative Variables

The survey included questions on quantitative variables and general information such as gender and nationality.

3.6.2. Qualitative Variables

The survey included questions on unstructured qualitative variables, including two questions on individual experiences related to barriers and facilitators to implementing personal medicine, and five questions on the implementation of this concept. This article shows only results relevant to the goal of the study. Example questions:

"In your opinion, what are the most important facilitators and barriers to public use of personalised medicine? What do the barriers/facilitators relate to (types of barriers identified, e.g., health care system, government, and PM users)? Please list and explain them briefly."

3.7. Ethics Approval

The survey was ethically approved by the Bioethics Committee of the Medical University of Wroclaw under the number KB0450/2020. The participants of the conference and workshops were asked for their consent to record and use their statements; the permission was granted.

4. Results

4.1. Systematic Reviews of Barriers and Facilitators of eHealth and mHealth

There were 5337 records identified using Medline and Academic Search Ultimate (Figure 1). The keywords used throughout the research process were: m-health or e-health, barriers and facilitators, and challenges and chronic diseases. The literature search identified a total of 5337 potentially relevant studies. Studies were eligible if they were published in peer-reviewed academic journals, written in English, and full text was available. Of the remaining 1504 records, 1187 were excluded after title and abstract assessment, and 297 were excluded after full-text analysis. The remaining 22 studies were analysed. The following Tables 1 and 2 shows the overview of the results.

Table 1. Overview of the results—barriers.

	Barriers to eHealth and mHealth Implementation in Chronic Diseases	References
Individual	- lack of awareness of eHealth and mHealth services	[7,9,18,21,22,24,27]
	- lack of experience and knowledge	[10–12,14,17,18,20,22,25]
	- lack of necessary equipment	[8,12,20,24]
	- lack of motivation	[10,20,23–25]
	- cost of new technology, lack of access to electronic devices	[7–9,12,17,20,24]
	- lack of or limited trainings	[7,9,17,21,26]
Technological	- user-friendly technical tools	[7,9,10,12,14,18,22–24,28]
	- safety precautions	[11,15,18–21,23–26,28]
	- poor/unreliable internet	[8,9,14,17]
Organizations, policies, legislation	- lack of integrated care policies	[7,11,13,26]
	- financial barriers: financial concerns, financial constraints	[8,17,20,22]
	- lack of trust between organizations, data sharing	[9,11,15,19,20,22,23,27,28]

Table 2. Overview of the results—facilitators.

	Facilitating Factors for eHealth and mHealth Implementation in Chronic Diseases	References
Individual	- motivation to change lifestyle change, learning about health	[7–9,12,22,24]
	- improving self-management skills, self-health monitoring	[7,8,14–17,19,21,23–25]
	- reducing the number of hospitalisations	[16,22]
	- eHealth and mHealth saving time	[7,20,22]
	- suport from family and/or caregivers	[17,18,22,23]
	- increase in physical activity and mental stimulation	[16,22]
	- improved connection and communication with physician	[7,8,11,15–17,20]

Table 2. *Cont.*

	Facilitating Factors for eHealth and mHealth Implementation in Chronic Diseases	References
Technological	- globally standardised coding schemes	[28]
	- easy to use eHealth software	[8,12,17,22,24,27]
	- ability to use eHealth applications via mobile devices	[20,22,26]
Organizations, policies, legislation	- implementation of international legislation, e.g., GDRP and Directive 95/46/EC	[28]

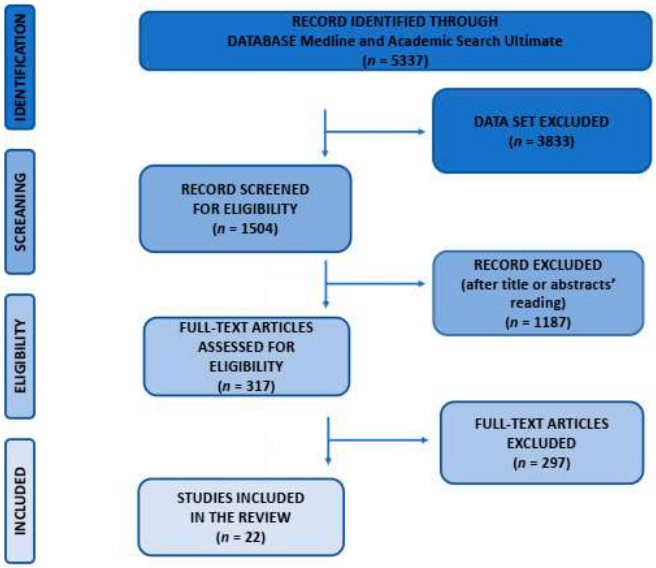

Figure 1. Flow diagram of identified and included records, according to PRISMA guidelines.

For the record identified through Medline and Academic Search Ultimate databases (articles published between 2015–2022), $n = 5337$.

For the dataset excluded (abstracts only, published in peer-reviewed academic journals, in English), $n = 3833$.

Full text articles screened for eligibility $n = 1504$.

Exclusion of articles after reading title and abstracts $n = 1187$.

Exclusion of articles after full text analysis $n = 297$.

Full text studies included in the qualitative synthesis $n = 22$.

4.2. Participants and Descriptive Data—Survey

The next step was an online survey of women and men associated with research institutions, private funders, policy makers, policy advisors, project managers, researchers, patient advocates, physicians, scientific officers, and health science consultants.

The research conducted made it possible to identify the barriers and facilitators observed in European countries. The following Table 3 shows the expected barriers and facilitators to Quadruple Aim implementation (data from surveys). We also include additional conclusions from the surveys.

Identifying these barriers and facilitators will allow for the development of recommendations to reduce barriers to the implementation of eHealth and mHealth in chronic diseases.

As mentioned in the survey, the lack of access to individual data, while ensuring their security, and the lack of digitialisation of medical data, are serious issues [AR_IT]. Another obstacle is the regional fragmentation of healthcare, which makes it difficult to share data, or implement PM measures [MN_ES] and the not very widespread use of data and supporting data (apart from classical laboratory tests) [SB_DE]. Data collected in the surveys suggest that the next main barriers to adoption of eHealth and mobile health services are seniors'

lack of knowledge [AT_IT], but also the lack of user-friendly technology [EB_IT] and a simple interface [AHA_TR].

Table 3. Expected barriers and facilitators for the implementation of the Quadruple Aim [29].

Quadruple Aim	Barriers for the Implementation of Personalised Medicine Interventions	Facilitators of the Implementation of Personalised Medicine Interventions
improving the individual experience of care	- lack of awareness of PM services - lack of skills of elderly people	- increased number of training sessions/conferences showing the possibility of PM - communications and informing citizens of the benefits of PM
improving the health of populations	- mainly specialised and service-centred, rather than patient-centred - lack of a user-friendly technology - access to individual data at the same time, guaranteeing their security - medical digital solutions are overly fragmented due to national legislations derogating GDPR/national evaluation - conflicts between regional and national competencies	- diffusion of patient-centred approaches - availability of personalised data as the basis for a decision for a personalised diagnosis and treatment
reducing the per capita cost of healthcare	- lack of financial incentives provided to HCPs to experiment with such solutions - some managed care executives feel that PM will increase the cost of prescription medicines	- mutual recognition for medical digital solutions published in other EU member states - centralised evaluation system and transparency between reimbursement rates of national healthcare systems
improving the experience of providing care (the importance of physicians, nurses and all employees finding joy and meaning in their work)	- lack of training for healthcare staff - lack of investments in healthcare	- patient advocates and cooperation with researchers and open-minded physicians - healthcare providers that can provide direct contact with patients and explain better the benefits of a PM treatment to them

Surveys show that both facilitators and barriers are related to the management, organisation, and functioning of (public) healthcare systems. PM (personalised medicine) solutions should work in synergy with the system to increase the value of healthcare to patients. Too often, PMs create specific/individual silos that are not aligned with the system and only exacerbate the fragmentation of the system. As a result, they very soon become classified as "gimmicks" and disappear [TP_PL]. Progress in PM can only be achieved through increased awareness among patients and caregivers, (HCPs are already aware of this) and policy makers (regulators, policy makers) who need to understand the potential and pathway of PM. There is a need for training and conferences for the general public, as well as roundtables and workshops to promote dialog between agencies/regulators/policy makers and clinicians/researchers in the field of PM [MV_IT]. While patients are optimistic about personalised treatment, they are not familiar with the principles of personalised medicine. Users of personalised medicine can be considered as facilitators, as they can contribute to the dissemination of the principles and their personal experiences [MD_GR].

An information campaign on the scale of pharmaceutical or automobile advertising should be undertaken. Specifically, public resources run by professionals to provide truthful, verifiable, and understandable information to the public. This should be supplemented by podcasts, TV, and YouTube documentaries, and by prominently placed and supported web content [MW _DE]. Patient associations should also be established. They can represent patients and citizens [MN_ES].

Meaningful integration of PM requires several paradigm shifts in both public option and decision making. Citizens need to be much better informed about personalised medicine, i.e., healthy people and NOT patients; this is far too late, because more than half of PM options are already over by the time one becomes a patient [MW_DE]. Like any radical change in an industry that has never focused on individualising citizens, the

introduction of personalised medicine is likely to be met with resistance. This could be related to the unwillingness of health professionals to change their current practices and the unwillingness of the industry to make large investments until it is absolutely certain of a payoff [MA_IT].

Respondents emphasised that there are many facilitators for eHealth and mobile health adoption in Europe. One of these is communication and education of citizens about the benefits of these solutions [KR_EE]. In some countries, personalised data already serve as a decision-making tool for personalised diagnosis and treatment [GK-J_DE]. As interviewees emphasised, healthcare providers can ensure direct contact with patients and better explain the benefits of eHealth and mobile health services [MCN_ES], and teach patients how to take care of their mental and physical health.

Personalised medicine also requires a different approach to patients by health professionals [KZ_PL], who can engage directly with patients and better explain the benefits of PM treatment to them [MN _ES]. It is pointed out that there is a lack of training of health professionals and the lack of investment in health care [MFG_ES].

It is noted that there is a lack of infrastructures and homogeneous regulations that allow stakeholders to practice personalised medicine [MS_DE]. Medical digital solutions are too fragmented due to national legislations that deviate from GDPR/national assessment [JT_FR]. A centralised assessment system and transparency between reimbursement rates of national healthcare systems [JT_FR] are also important.

Barriers often arise from regulations (e.g., privacy laws that hinder the use/reuse of personalised information, or regulatory issues that limit the ability to prescribe innovative and personalised methods because the process to get them reimbursed by the public health system can be very slow) [MV_IT].

4.3. Participants and Descriptive Data—Conference

Many pilot eHealth and mHealth projects in chronic diseases are being conducted worldwide. Based on the Regions4PerMed project, the results of the conferences, workshops, and best practices brochures of the Regions4PerMed project for selected existing solutions in the field of personalised medicine have been compiled in a Table 4.

Table 4. Existing solutions in the field of personalised medicine—a synthesis based on the Best Practices Booklet within the Regions4PerMed project [2,30–32].

Project Initiative Title	Country	Key National Solutions
Return of genomic data to biobank participants, personalised medicine pilot projects in Estonia	Estonia	The aim of the pilot projects supported by the Estonian Research Agency RITA: development and gradual implementation of the rules, procedures, and principles necessary for the introduction of personalised medicine for general practitioners and specialists. During the project, more than 2000 biobank participants received genetic feedback and were further researched and treated by primary care physicians, oncologists, and medical geneticists as needed. Project website: https://genomics.ut.ee/en (accessed on 19 February 2022) [30]
Onkolotse (Cancer guide)	Germany	Improve personal support for cancer patients and their families along the treatment pathway and across all medical settings (idea: one face to the patient). Onkolotse will help patients and their families to find their personal path through cancer treatment, become informed patients, improve treatment adherence and coping, and help them live with the disease and make the most of their lives. Project website: www.nweurope.eu/codex4smes (accessed on 19 February 2022) [31,32]
How the Techforlife cluster can support and improve Lombardy's healthcare system	Italy	The main challenge is to use technology to provide a high standard of care in the daily lives of people with chronic diseases; in particular, ensuring a personalised motor and cognitive rehabilitation process while improving the quality of life of patients. The goal is to focus on the monitoring and safety of patients in their homes, to create technological innovation through a high-level scientific approach that is fostered by multidisciplinarity and technology transfer, including the implementation of efficient business models. Project website: https://cluster.techforlife.it (accessed on 19 February 2022) [30]

Table 4. *Cont.*

Project Initiative Title	Country	Key National Solutions
Organisational and digital development in the care of chronically ill patients	Italy	ASST Vimercate has a defined process that enables the proactive "care" of chronic and frail patients, including the definition of different professional roles, the introduction of an outsourced service centre to manage care activities, the introduction of the role of "case manager" to ensure the quality of the process and care. In addition, ASST Vimercate has begun to use "Big Data Analytics" technologies to develop predictive algorithms that help professionals in the early detection of patients with certain chronic diseases and the occurrence of complications. Project website: https://www.asst-brianza.it/web/ (accessed on 19 February 2022) [30]
Virtual coach and chatbot interactions for cognitive enhancement	Italy	The main challenge is to provide outcome-based integrated care to older people to improve their quality of life and that of their families, while making European health and social care systems more sustainable, and to build an integrated care system between health and social services by proposing an app-based platform that connects informal and formal caregivers and supports with health empowerment through a virtual coach. Project website: https://www.israa.it/home-europa (accessed on 19 February 2022) [2]
BIOCAM—AI approach to doctor's workload reduction	Poland	BIOCAM is a start-up company developing innovative capsule endoscopy that enhances patients' comfort of life and provides new healthcare solutions. The most common diseases that can be screened with capsule endoscopy are Crohn's disease, celiac disease, small bowel tumors, and anemia of unexplained cause. The endoscopy capsule is only 11 mm wide and 23 mm long. Project website: https://biocam.pl/ (accessed on 19 February 2022) [2]
Cardiomatis	Poland	The cloud tool speeds diagnosis and increases efficiency for cardiologists, clinicians, and other healthcare professionals in interpreting ECGs, automating the detection and analysis of about 20 cardiac abnormalities. The software integrates with more than 25 ECG monitoring devices and offers an advanced cloud software interface as a differentiator from traditional medical software. Project website: https://cardiomatics.com/ (accessed on 19 February 2022) [2]
Glucoactive—control diabetes, everywhere, always	Poland	Innovative technology enables non-invasive, automatic measurement of blood glucose levels. The proposed telemedicine solutions, including online storage, enable fast and accurate measurement, as well as features known from premium-class smartwatches. The devices have no replaceable elements such as strips or sensors, they are a one-time purchase, which means cost savings compared to invasive devices. Project website: www.gluco-active.com (accessed on 19 February 2022) [2]
Infermedica	Poland	Infermedica is developing its diagnostic engine to collect admissions, verify symptoms, and guide patients to the right treatment. The company uses artificial intelligence and machine learning to evaluate symptoms and find patterns in the data. The medical team reviews every piece of information added to the medical database to ensure patients receive safe and reliable recommendations. Infermedica develops mobile, web, and chatbot apps that are easy to use and integrate. Project website: https://infermedica.com/ (accessed on 19 February 2022) [2]
Patient Rescue Support Project Wrist-Band Device	Poland	The aim is to develop an innovative care concept tailored to solving the problems associated with demographic change. The wrist-band device can work in two ways: 1. It collects basic data (real-time physiological signals) on the wrist to help a person with frailty, without having to call the emergency services. The data from the wristband ID is transmitted to the dispatcher; 2. It can give doctors and medical staff access to clinic data. Project website: http://www.wrp.info.pl (accessed on 19 February 2022) [2]
StethoMe®	Poland	The company has developed an intelligent solution to improve diagnosis in primary care. StethoME is an AI-powered healthcare solution that enables automated and remote lung and heart exams. It provides the telemedicine solution with the missing piece of the puzzle of remote interaction between the professional, the physician, and the patients themselves. Project website: https://stethome.com/ (accessed on 19 February 2022) [2]
HAITool—A real-time hospital infection surveillance and hospital-wide intelligent clinical decision support system	Portugal	To solve the problem of multiple sources of hospital/patient data, a web-based information system was developed that supports an SQL server that extracts and summarises patient data, microbiology laboratory results, and pharmacy data. Data are extracted at regular intervals from hospitals' existing information systems by an ExtracteTransformationeLoad (ETL) module, using intelligent automated routines and then being processed and aggregated in a single data warehouse. Project website: http://www.haitool.ihmt.unl.pt (accessed on 19 February 2022) [30]
NAGEN 1000: An example of a project for regional implementation of personalized genomic medicine in healthcare	Spain	"NAGEN 1000" is a pilot study to integrate recent advances in modern genomic technology into clinical practice. The study mainly targets patients with rare diseases and their families. The whole-genome data provide answers not only for rare diseases, but also for the field of personalised prevention by analysing genetic factors associated with the risk of serious, preventable diseases. In addition, the analysis of pharmacogenomic variants provides initial insights into the type and dosage of certain drugs that are tolerated by individuals. Project website: https://www.nagen1000navarra.es (accessed on 19 February 2022) [30]

5. Discussion

As noted by Wilson et al. (2021), rapid population ageing has become a global phenomenon. In 2018, the number of seniors exceeded the number of children for the first time in history. From the data they presented, they will account for 22% of the world's population in 2050. This is one of the most important reasons to ensure adequate planning and delivery of health and support services [9].

Older people require many more multicomponent interventions; they tend to be more vulnerable not only to chronic diseases but also to side effects of their treatment, to which patients may respond very differently when these effects are influenced by age. Limited income or insurance coverage, limited mobility, disability, rural or remote location, and negative self-perception of ageing (associated with lower health-related quality of life) should also be considered [3,9,10,33]. Therefore, both electronic health services (eHealth) and mobile health services (mHealth) are becoming indispensable components of healthcare. eHealth/mHealth encompass a wide range of healthcare services, from electronic prescribing and access to medical records to text messages reminding patients to take their medications. Therefore, eHealth and mHealth are becoming important components of healthcare delivery [34].

5.1. Chronic Diseases Management

Adherence to chronic disease management is critical for better health outcomes, quality of life, and cost-effective healthcare. Mobile technologies are increasingly being used in health care and public health practice (mHealth) for patient communication, monitoring and education, and facilitating adherence to chronic disease management [35].

Mobile health technology (mHealth) supports medical practice. It has proven useful in daily self-management of chronic diseases by patients themselves or in remote medical management. The processing, sensing, and communication capabilities of mobile devices such as smartphone applications, web-based technologies, telecommunication services, social media, and wearable technologies are becoming increasingly popular. This has led to their use as the main technology for providing comprehensive health services [36,37].

In recent years this has led to a strong focus on promoting "self-management" among chronically ill patients. Although patients who are more knowledgeable about their disease, health, and lifestyle (especially when they are responsible for managing their own health and disease) have better experiences and health outcomes and often use fewer health resources, it is noted that limited knowledge about self-management can further limit health behaviours in patients with chronic disease [3,11]. To overcome this barrier, lifestyle changes and an approach called "self-management" of chronic disease are needed. It is important to empower patients to actively participate in health management with a focus on complete physical well-being. This includes introducing innovative approaches to existing health care such as medical management and changing, maintaining, and creating meaningful behaviours [11,38].

5.2. System for the Collection of Medical Data in Chronic Diseases

One of the main objectives in electronic health services (eHealth) and mobile health services (mHealth) is to use medical data collection systems in chronic diseases [34].

Another goal is to increase knowledge and strengthen the citizens' and community's participation in the surveillance system. Inadequate access to medical data and a lack of confidence in its quality are the main causes of underutilisation of ICT [34].

It is very important to link data between different local data centres, in order to make treatment decisions [2]. Both evidence and data infrastructures capable of collecting and analysing data are needed. For this reason, more investments should be made in these areas [2].

Integration is needed in defining new standards for topics such as cross-platform authentication and data exchange. Standardisation in healthcare services is an important prerequisite for improving patient care through the use of modern technologies. The devel-

opment of standards is very important to ensure the interoperability of information systems, i.e., to enable them to communicate with each other and to enable eHealth projects around the world. Therefore, it is necessary to develop new and comprehensive standards [2]. The highly personalised data captured by digital health technologies can improve the relationship with patient outcomes and treatment adherence, and enable broader use of value-based care models. They enable both informed decision making and the delivery of personalised care [39,40].

5.3. Use of eHealth and mHealth by Older People

There are still barriers to the adoption and use of eHealth by older people.

Nevertheless, it is observed that the use of information and communication technology by the elderly is increasing and is considered positive and important in their daily lives. This considerable potential makes it possible to better meet the health needs of older people. The design of digital health services must be based on the specific needs of older people. The main barriers related to the functionality of eHealth platforms and related issues are the lack of an age-appropriate interface, small screens, small texts, etc. However, there are other age-related barriers that affect the usability of mHealth. These include lack of knowledge about how to use mHealth, high cost of new technologies, and limited/fixed income. Very often, mobile technologies are too difficult to use. Seniors can be overwhelmed by new information and alerts. In summary, when developing eHealth services for seniors, it is very important to include features such as audio feedback, a large text size, and a notification system that allows users to choose how and when they are notified so they can engage with the platforms that work best for them. Increasing this awareness influences the detection and effective management of chronic diseases and the reduction of their prevalence in the population [10,12,41,42].

Increasing awareness influences the detection and effective management of chronic diseases and the reduction of their prevalence in the general population. The initiative focuses on older people and their needs in terms of prevention and management of frailty. Health systems integration is multidimensional and complex, involving multiple stakeholders. Future challenges and vulnerable health systems require smart solutions that support the continuum of care for frail patients [2].

5.4. Patient Engagement in eHealth and mHealth

There is growing evidence that better-informed patients improve their self-care and medication adherence and enhance their health and well-being. The ability of citizens to access data is also considered important for reasons of improving disease management as a new form of patient engagement and empowerment [2].

For consumers who use mobile devices to access their medical records through online portals, a good experience is more than a matter of convenience. A recent study shows that it can lead to patients staying in touch with their primary care physician more regularly and requiring fewer hospitalisations. A Kaiser Permanente study that pooled diabetes patients from 2006 to 2007 [43], and patients with multiple chronic conditions, confirmed that those who connected with health resources via smartphones, tablets, or computers had better outcomes [44]. Similarly, research by Lee et al. (2018) on the impact of mHealth app feature usage patterns on user engagement showed that users used the app the most at the time of launch, and their usage gradually declined over time. The research suggests that frequent and regular use of the self-monitoring function significantly reduces the likelihood of abandoning the app. Thus, sustained use of mHealth apps is closely associated with regular use of the self-monitoring function [45].

In Poland, for example, the National Health Fund should and will continue to develop the potential for providing tools for patients and healthcare providers to facilitate patient–doctor communication, by introducing a new type of service based on telemedicine and telehealth diagnostics that enables patients to manage their own health. The primary care

physician's team should take care of them because they have a better and closer contact with patients and know their needs [2].

5.5. eHealth and mHealth—Quality of Life

There is an urgent need to transform health care systems as the population ages rapidly and the prevalence of chronic disease and comorbidity continues to increase. Therefore, it is critical to adapt the way patients and medical professionals communicate and collaborate to promote health. This is the only way to meet future expectations for high-quality, patient-centred care [39]. Healthcare services need to prioritise care for people with multiple chronic conditions (multimorbidity) and this seems to be best accomplished through integrated and patient-centred approaches to adequately meet patients' needs. Despite the increasing investment and interest in eHealth, there are still some challenges to overcome to enable wider and more systematic adoption of ICT in healthcare. Health services and systems must become more resilient, effective, equitable, accessible, sustainable, and comprehensive. Transformation and adaptation require a digitally oriented mindset [2].

The application of eHealth solutions can provide chronically ill patients with high-quality care that satisfies both patients and healthcare professionals, while reducing health-care consumption and costs [3].

5.6. Integrated Care Policies

The main challenge for national and regional authorities is to coordinate regional PM policies and innovation programs, to improve system integration and patient management, and to accelerate the use of PM for citizens and patients [46]. Also, very important at this moment is the lack of an eHealth policies that would promote effective strategies for adoption by clinicians [13].

The surveys also showed that there is a great need for mutual recognition for medical digital solutions published in other EU Member States.

In addition, the conference highlighted that eHealth and mHealth also require not only cross-border and interdisciplinary collaboration in chronic disease management, but also stakeholder engagement [2].

5.7. Healthcare Providers in Chronic Diseases

Citing the need to find innovative solutions to meet the needs of citizens, new technologies are expected to transform health care delivery. Any holistic method of delivering health services to the public should improve health care by optimising physician–patient relationships. The improvement of health care should be achieved through the introduction of user-friendly technological tools that are easy to use for patients of all ages [47].

It was also pointed out that developing the potential to provide patients and health care providers with proven tools will facilitate the patient's communication with the physician by introducing a new type of service based on telemedicine and telehealth diagnostics, while empowering the patient to manage his or her own health; that technology can help detect emergencies and assist healthcare professionals by providing them with early access to health information and recommendations [2].

6. Limitations of the Study

This review has some limitations. The search was limited to articles published in English, or only English-language papers were included. The exclusion of articles in other languages may have limited access to studies with significant results related to our objective. To overcome this limitation, PubMed/MEDLINE and Academic Search Ultimate databases were searched for studies published in English between 2020 and 2021.

Survey data and conference data also have limitations. The number of participants may be considered an insufficient sample size for statistical measurement. The content of the questions may also be considered a limitation of the study. However, it is important to note that the questions were approved by the supervisor (professor with experience in qualitative

and quantitative research) and that the questionnaires were sent to the stakeholders of Regions4PerMed: the lecturers of the conferences and workshops, and the participants of these events. This methodology allows for analysis of experiences related to barriers and facilitators to implementation, based on evidence from existing implementations of innovative eHealth interventions at the micro-, meso-, and macroregional levels within health and social systems, particularly related to chronic disease management. Conference participants included experts from academia and industry, as well as representatives of regional and governmental health policy institutions from a variety of EU countries.

7. Conclusions

The increasing burden of chronic disease requires innovative approaches to chronic disease prevention and management. Much has already been done to improve the quality of life in chronic diseases through personalised medicine. The use of technological solutions improves diagnostics and the treatment decision-making process, enables better customisation of treatment, and reduces its time and cost. eHealth facilitates diagnostics, prevention, and treatment. The concept of eHealth aims to break down barriers so that healthcare providers (government agencies, hospitals) can work more closely together.

However, there are still barriers to the development of eHealth, such as inconsistent legislation. The main obstacles to collaboration with government agencies are bureaucracy and lengthy legislative procedures. It should also be remembered that the computer level in medical institutions is low and there is a lack of well-trained personnel and coherent global platform. To enable further development of eHealth and mHealth electronic medical records and medical event registration are needed.

In summary, medical technologies in the areas of prevention, diagnosis, treatment, and rehabilitation occupy an important place in home care, ambulatory care, and hospital departments. Medical technologies for home care can help modulate home care and make it more effective in terms of cost and treatment time. With the advent of new technologies that increase the efficiency of health care delivery, it is critical to improve the population's competence in using these technologies.

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Article

Barriers and Facilitators to the Implementation of Personalised Medicine across Europe

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Abstract: (1) Background: Personalised medicine (PM) is an innovative way to produce better patient outcomes by using an individualised or stratified approach to disease and treatment rather than a collective approach to treating patients. PM is a major challenge for all European healthcare systems. This article aims to identify the needs of citizens in terms of PM adaptation, as well as to provide insights into the barriers and facilitators categorised in relation to key stakeholders of their implementation. (2) Methods: This article presents data obtained from the survey "Barriers and facilitators of Personalised Medicine implementation—qualitative study under Regions4PerMed (H2020) project". Semi-structured questions were included in the above-mentioned survey. The questions included both structured and unstructured segments in an online questionnaire (Google Forms). Data were compiled into a data base. The results of the research were presented in the study. The number of people who participated in the survey can be considered an insufficient sample size for statistical measurement. In order to avoid collecting unreliable data, the questionnaires were sent to various stakeholders of the Regions4PerMed project, which includes members of the Advisory Board of the Regions4PerMed Project, but also speakers of conferences and workshops, and participants in these events. The professional profiles of the respondents are also diverse. (3) Results: The insights on what would help in the adaptation of Personal Medicine to citizen needs have been categorised into 7 areas of need: education; finances; dissemination; data protection/IT/data sharing; system changes/governmental level; cooperation/collaboration; public/citizens. Barriers and facilitators have been categorised into ten key stakeholders of the implementation barriers: government and government agencies; medical doctors/practitioners; healthcare system; healthcare providers; patients and patient organisations; medical sector, scientific community, researchers, stakeholders; industry; technology developers; financial institutions; media. (4) Conclusions: Barriers to the implementation of Personalised Medicine are observed across Europe. The barriers and facilitators mentioned in the article need to be effectively managed in healthcare systems across Europe. There is an urgent need to remove as many barriers as possible and create as many facilitators as possible to implement personalized medicine in the European system.

Keywords: Personalised Medicine; interregional cooperation; barriers; facilitators; healthcare systems

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1. Introduction

Personalised Medicine (PM), as highlighted by Fournier et al., (2021), for example, is becoming an issue in health policy and in the media. Importantly, and highlighted by the authors, there is no consensus in the scientific literature on the definition of PM. The same term is defined emphasizing both patient-centred and biomedical aspects [1]. PM is further complicated by the synonymous use of terms such as precision, personalised, stratified and targeted medicine [2]. The term PM and what it involves, as pointed out by Botham et al., (2021), is still largely unfamiliar to the public [2], and is relatively new in medical society [3]. The Horizon 2020 Advisory Group of the European Commission defines PM as "a medical model using characterization [sic] of individuals' phenotypes and genotypes

(e.g., molecular profiling, medical imaging, lifestyle data) for tailoring the right therapeutic strategy for the right person at the right time, and/or to determine the predisposition to disease and/or to deliver timely and targeted prevention".

Although personalised medicine is becoming the new paradigm for the management of certain diseases, the economics of personalised medicine has only focused on assessing the efficiency of specific treatments, and lacks a theoretical framework analysing the interactions between pharmaceutical companies and healthcare systems, leading to the implementation of personalised treatments [4].

PM is rooted in the belief that, since individuals possess nuanced and unique characteristics at the molecular, physiological, environmental exposure and behavioural levels, they may need interventions for diseases they suffer from that are tailored to these nuanced and unique characteristics [5].

PM is strongly developing because the influence of individual characteristics on disease progression and the efficacy of medication is becoming more evident. Some people have, due to their genetic makeup, a higher risk of severe side effects when using specific medication. Others are more sensitive to the medication and need a different dose than generally recommended. In addition, the genetic characteristics of tumours in cancers may differ from patient to patient, which creates opportunities to fine-tune the therapy based on tumour characteristics [3].

The application of PM requires having instruments (tests) to stratify patients, as well as personalised treatments [6].

The implementation of PM in clinical practice requires smart planning and a structured approach to ensure quality and long-term sustainability [7]. The integration of PM into mainstream healthcare will only be successful, as noted by Holde at al. (2019), if the public understands and supports this change [8].

Leaders of countries and major healthcare organisations are pushing for rapid translation of these discoveries into benefits for patients. However, shifting to "an innovative approach that takes into account individual differences in people's genes, environments, and lifestyles" from the existing "one-size-fits-all" approach to healthcare requires a better understanding of this new approach by the public and other stakeholders [1].

2. The Aim of the Study

The aim of this study was to investigate and identify the interventions that would remove the barriers to the implementation of innovative interventions and to identify the best practices implemented in the European countries which support the implementation of innovative interventions in the field of PM.

3. Materials and Methods

3.1. Ethics Approval

This study was approved by the Bioethics Committee of the Wroclaw Medical University under number KB0450/2020.

3.2. Study Design

To address the subject of the study, a semi-structured questionnaire "Barriers and facilitators of Personalised Medicine implementation—qualitative study under Regions4PerMed (H2020) project" was developed. The entire survey has been added as the Supplementary Materials File S1.

The survey included demographic questions regarding age, gender and nationality, which allowed us to better understand the background of the respondents. The survey also included two questions related to individual experiences with barriers and facilitators of PM implementation, and five questions about the implementation of PM itself.

3.3. Study Design

This study analyses data from the online semi-structured survey "Barriers and facilitators of Personalised Medicine implementation—qualitative study under Regions4PerMed (H2020) project".

For this purpose, the above-mentioned survey was designed. This semi-structured questionnaire includes items with some pre-categorised response options and additional open-ended options. It includes general information on gender and nationality, two questions on individual experiences with barriers and facilitators of PM implementation, and five questions about the implementation of PM itself. The survey responses were coded in the following format—a country symbol and a number indicating the order in which the surveys were delivered.

3.4. Questionnaire Development and Data Collection

Participants

Stakeholders of the Regions4PerMed (Interregional Coordination for a Fast and Deep Uptake of Personalised Health) project, which includes members of the Advisory Board of the Regions4PerMed Project, lecturers at conferences and workshops and participants in these events, were asked to complete the semi-structured survey.

Data were collected from 85 respondents. Interviewees came from 20 countries, including Ukraine (UA), Italy (IT), Germany (DE), Spain (ES), Poland (PL), Denmark (DK), Belgium (BE), Great Britain (GB), Latvia (LV), Canada (CA), Estonia (EE), Turkey (TR), Romania (RO), Europe (EU), France (FR), Lithuania (LT), Sweden (SE), Greece (GR), Netherlands (NL), Portugal (PT) and Kazakhstan (KZ). The age of respondents ranged between 24–74.

The participants include researchers (scientists), entrepreneurs, scientific officers, policy officers, policy advisors, project managers, physicians, civil servants, lawyers, public health experts, health care managers, biostatisticians, health care consultants, etc.

3.5. Variables

3.5.1. Quantitative Variables

The survey included demographic information on quantitative variables, such as age, gender and nationality.

3.5.2. Qualitative Variables

The survey collected responses to questions on individual experiences related to the barriers and facilitators to implementing PM, and responses to five questions on the implementation of this concept.

In this paper, only the results that are relevant to the aim of the study are presented.

3.6. Data Sources

The presented research analyses is sourced from the collected data obtained from online semi–structured surveys (survey "Barriers and facilitators of personalised medicine implementation—qualitative study under Regions4PerMed (H2020) project", author of the survey—Dorota Stefanicka—Wojtas).

3.7. Study Size

Between July 2020 and November 2022, 85 surveys were conducted. Semi-structured questions were included in the above-mentioned survey. The questions included both structured and unstructured segments in an online questionnaire (Google Forms). The data were compiled into a database. The results of the research were presented in the study.

4. Results

This section is divided by subheadings. It should provide a concise and precise description of the experimental results and their interpretation, as well as the experimental conclusions that can be drawn from the study.

4.1. Participants and Descriptive Data—Survey

The results from the semi-structured survey "Barriers and facilitators of Personalised Medicine implementation—qualitative study under Regions4PerMed (H2020) project" are presented below.

The survey shows the rate of public awareness of PM (exact question—*Given your professional experiences, please rate your public awareness of PM on a scale from 1 (low) to 5 (very high). How well are the citizens informed about PM*) Figures 1–3 shows the data by the rate of public awareness of PM overall and by the nationality of the respondent.

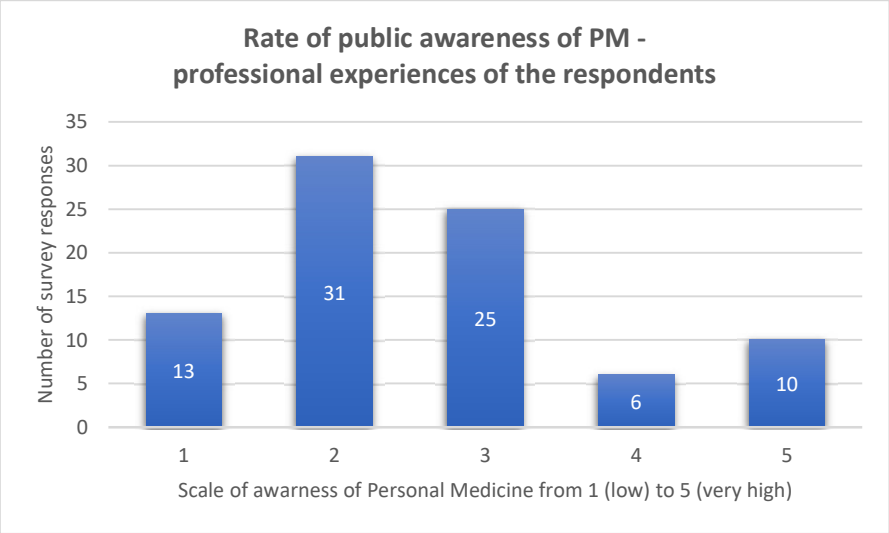

Figure 1. Rate of public awareness of PM—professional experiences of the respondents (survey data).

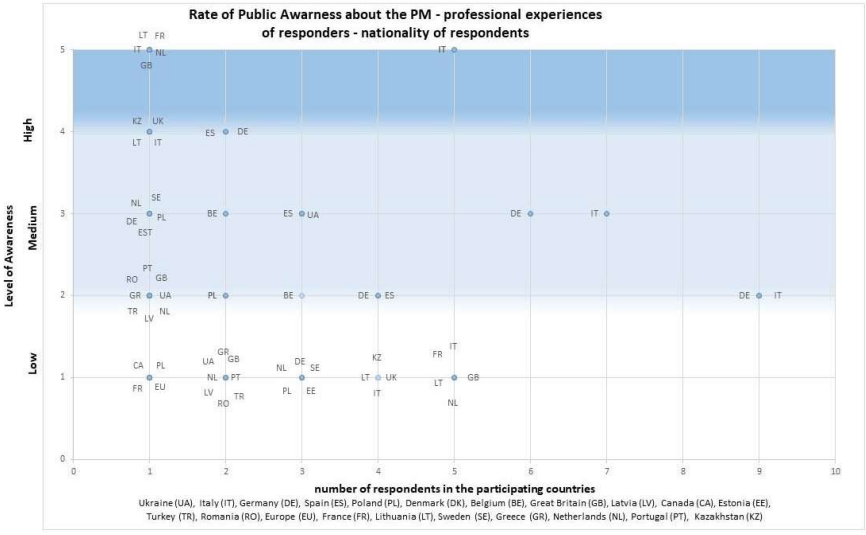

Figure 2. Rate of public awareness of PM—professional experiences of the respondents—breakdown by respondents' nationality (survey data)—dot plot.

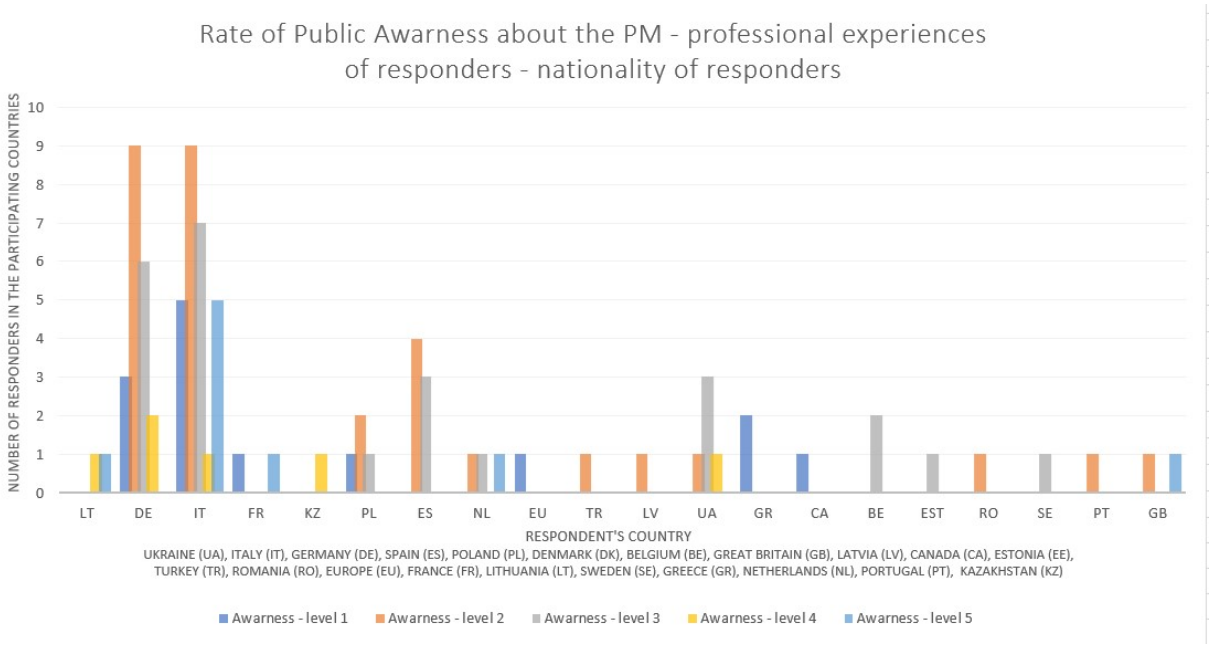

Figure 3. Rate of public awareness of PM—professional experiences of the respondents—breakdown by respondents' nationality (survey data)—bar chart.

Below, in the Table 1, the authors have presented the comparison of the public awareness of PM in a particular country of respondents, data about low, middle and high-income, and their country's GDP per capita.

Table 1. Comparison of the public awareness of PM in a particular country of respondents and their country's GDP per capita.

Country	Rate of Public Awareness of PM	Number of Survey Responses	Country's GDP (in USD) per capita (2022 Year—Estimated Data)—Source of Data—The International Monetary Fund	Division of the Countries—High-Income, Middle—Income, Low—Income Country Source of Data—World Bank List of Economies 2022
Ukraine	2	1	4862 (2021)	Lower middle income
	3	3		
	4	1		
Turkey	2	1	9961	Upper middle income
Kazakhstan	4	1	11,591	Upper middle income
Romania	2	1	15,619	Upper middle income
Poland	1	1	19,023	High income
	2	2		
	3	1		
Greece	1	2	20,876	High income
Latvia	2	1	21,482	High income
Lithuania	5	1	24,032	High income
	4	1		

Table 1. *Cont.*

Country	Rate of Public Awareness of PM	Number of Survey Responses	Country's GDP (in USD) per capita (2022 Year—Estimated Data)—Source of Data—The International Monetary Fund	Division of the Countries—High-Income, Middle—Income, Low—Income Country Source of Data—World Bank List of Economies 2022
Portugal	2	1	24,910	High income
Spain	2	4	29,198	High income
	3	3		
Estonia	3	1	29,344	High income
Italy	1	5	33,740	High income
	2	9		
	3	7		
	4	1		
	5	5		
European Union	1	1	37,280	
France	1	1	42,330	High income
	5	1		
United Kingdom	2	1	47,318	High income
	5	1		
Germany	1	3	48,398	High income
	2	9		
	3	6		
	4	2		
	3	2	50,598	High income
Netherlands	2	1	56,298	High income
	3	1		
	5	1		
Sweden	3	1	56,361	High income
Canada	1	1	56,794	High income

The survey also shows how difficult it is to adapt PM to the needs of citizens (exact question—*Do you think Personalised Medicine can be easily adapted to the needs of citizens?*) According to 31 respondents, adapting PM to the needs of citizens is easy, while 54 respondents pointed out the difficulty of adapting PM to the needs of citizens.

Respondents were also asked for their own ideas about what would be helpful in adapting PM to the needs of citizens—the question referred to the previous question and was—*What could be helpful? Specify* (answers in alphabetical order).

4.1.1. Cooperation/Collaboration

What is crucial is close collaboration with general practitioners, more information for the citizen and support from general practitioners, cooperation between doctors working in hospitals and general practitioners. General practitioners are the first ones who can convince patients to try PM [DE_84]. Cooperation between patient advocates (they need PM), researchers and clinicians [DK_14], between industry, governments, international organisations and patient advocates [LV_23], as well as better cooperation between scientists

and physicians [DE_34], is also important. There also needs to be a direct link between GPs and research hospitals [IT_69].

Collaboration between regulatory authorities and healthcare managers is also important to mutually improve awareness about the topic [IT_41] and determine common intervention plans [IT_54].

4.1.2. Data Protection/IT/Data Sharing

In order to adapt PM to citizen needs, better and openly verifiable protection of PM data is important, so that patients feel confident enough to share it for their own needs and as part of aggregated data sets used for developing PM approaches for others [GB_80].

Barriers to accessing patient/citizen data should also be removed [IT_79]. Therefore, it is necessary to build data-sharing infrastructure [IT_28], because the support of technology in clinical decisions can put enormous amounts of data in the hands of physicians, facilitating their decision-making and allowing them to make the best choice for that particular patient [ES_10].

Pharmaceutical companies should commit to sharing data from all trials and clinical studies [GB_75] to increase the wide availability of data [DE_70].

4.1.3. Dissemination

Respondents emphasise the importance of better disseminating knowledge about PM [IT_64], [IT_29], [UA_85], [PL_48], sharing information in the media within the Medical Society [UA_31], increasing the quality of advertisements on TV and social media [IT_11] and organising meetings with all stakeholders, including patients [IT_53].

Public awareness plans and schedules for their integration need to be developed [DE_73], [IT_74]. It is also important to disseminate scientific research findings more widely among patients and citizens [ES_40].

4.1.4. Education

It is crucial to educate and discuss the concept of personal health—for a large forum of politicians and also for citizens [DE_2]. Education and cooperation between industry, governments, institutions, organisations and patient advocates [LV_23] are important.

It is also very important to raise awareness of the benefits of PM and the education of citizens [MD_IT].

Therefore, it is necessary to invest in patient literacy, involvement, engagement, empowerment, introduce changes in the university education and the lifelong learning programme for professionals (doctors, nurses, others) [IT_19].

More training needs to be organised and awareness must be raised among healthcare professionals, GPs and citizens [ES_76] [IT_69], among healthcare providers and payers [DE_70]. Better education of patients on the benefits of PM is of great significance [DE_37].

4.1.5. Finances

PM requires massive investments [IT_3]. Hard decisions may have to be made about the affordability of hyper-personalised medicine and the cost implications for other services. Better, more regularly updated guidelines, and evidence-based, data-driven decision support algorithms are needed to make this possible [GB_80].

The industry must improve the cost-benefit ratio;sickness funds/health insurances have to be regulated in such a way that they are interested in long-term health and cost reduction (and not just in short-term savings) and healthcare systems need to be oriented towards value-based healthcare [DE_83].

There should also be more investment in the digitisation of health data and interoperability [IT_8]. It is also important to change governance with appropriate financial incentives [EU_18].

Sustainable lighthouse projects and funding/frameworks for sustaining successful projects (these are often discontinued after the initial funding period) should be developed [DE_16].

The economics of healthcare are based on insurance and on the concept of "one-size-fits-all". Changing the economics through PM will have an impact on the whole health system [RO_42].

In addition, telemedicine/PM services should be reimbursed by the public health system, and there should be special funds for investment in PM solutions [PL_7].

4.1.6. Public/Citizens

Citizens might be the trigger for change. It needs to be explained to them what they would gain from PM [IT_49], and they should be engaged/involved in the decision-making process [ES_63]. It should also be known what problems healthcare providers and patients face at a local level to find the correct solutions [ES_40]. The citizen needs examples. It is necessary to create space for patients to ask, or even demand to move on to a better paradigm [IT_57].

Most importantly—patience is required, combined with a continuous effort to bring together stakeholders from many areas [DE_2] and easy-to-handle adoption strategies that help to bring new approaches into practise in an evolutionary, step-by-step process [DE_17].

4.1.7. System Changes/Governmental Level

For better dissemination of knowledge about PM, a system change is very important. It will be needed if PM is implemented on a large scale, which will require a lot of effort on many levels. The biggest mistake is to expect far-reaching, short-term successes [DE_2].

National and international guidelines for implementation and reimbursement [DE_20] should be developed. Political support for a PM oriented healthcare system should be established [SB_DE], and meaningful integration of PM requires several paradigm changes, both in the public option and in decision-making [DE_45].

According to respondents, there should also be a reform of the healthcare system [NB_UA], changing the systemic approach and dialogue with public actors and HTA agencies [PL_9], and governance should be changed through appropriate financial incentives [EU_18].

The influence of vested interests on the prioritisation of certain medicines must also be overcome [GB_80].

The survey also included a question about personal opinion on existing barriers and facilitators of the implementation of the PM (exact question—*What are, in your opinion, the most important facilitators of and barriers to the public use of Personalised Medicine? What are the barriers/facilitators related (types of identified barriers to, e.g., health care system, government, PM users)? Please list and explain them briefly below*) and a question about key stakeholders, to which the previously listed information can be assigned (exact question—*In your opinion, who are the key stakeholders of the implementation barriers you have listed above.)*

In Table 2, the authors have presented the analysis and comparison of the answers they received to these specific questions.

Table 2. Barriers and facilitators to the implementation of PM.

Key Stakeholders of the Implementation Barriers	Barriers to the Implementation of PM Interventions	Facilitators of the Implementation of PM Interventions (Ułatwienie)
Government and government agencies	- lack of clear and common public strategy on PM (IT_13) - certification and regulations (DE_24) - regional fragmentation of the health care system makes data sharing or the introduction of PM implementation policies more difficult, differences in national, regional and municipal responsibilities (SE_46), (ES_40), (IT_36), (DE_38), (ES_76), (IT_8), (IT_74) - regulatory hurdles for cross-sector innovation - collaboration (healthcare, industry, government, citizen/patient) (SE_46), (IT_41), (DE_39) - differences in national, regional and municipal responsibilities (SE_46) - delays in efficiently implementing GDPR (IT_28) - medical digital solutions are overly fragmented due to national legislations derogating from GDPR/national evaluation (FR_5) - authorities and Health Funds fear rising costs of PM today and at the same time not gaining the promised cost reductions in the future (DE_83) - traditional organisation models (IT_19) - public procurement rules (ES_50) - governance system (IT_19), (IT_60) - government in general (IT_44), (ES_40)	- government in general (IT_69) - government strategies and financing (ES_10), (ES_40), (ES_58) - government dialogue, education on the concept of personalised health for a large forum of politicians (DE_2), (IT_41) - government can contribute to making PM practice more widespread and its concept familiar to the general public (GR_27) - removing technical/legal barriers by harmonising processing of medical data (FR_5), (ES_58) - mutual recognition of digital medical solutions published in other EU member states (FR_5) - research centres and programmes, especially at the European level (IT_60) - the digitalisation of health data (ES_76) - the importance given to PM by the EC and national/regional governments (research funding, specific CSAs, national PM strategies, etc.) (ES_76) - public and private collaboration (ES_76), (ES_58)
Medical doctors/practitioners	- lack of awareness of data-intensive methods (IT_12) - lack of will of the healthcare professionals to change their current practice/accept the PM mode (IT_4), (DE_37) - medical doctors sceptical of artificial intelligence-based diagnoses (IT_12) - lack of access to individual data due to the need to guarantee their security (DE_34) - minor use of data and support by data (other than classic lab tests) (DE_37) - data used for evidence generation and clinical decision-making (quality, availability, level of impartiality) (IT_56) - lack of confidence (clarity of simulation models, repeatability, sensitivity, accuracy, etc.) (IT_56) - acceptability by the clinical world (IT_11) - lack of instructions for GP's, lack of clear communication (IT_69) - insufficient published data (DE_32) - lack of medical doctors with training and ability to explain complex decisions regarding risk factors, efficacy and choices related to data sharing (GB_80), (LV_23) - lack of information flow from medical doctor to patient because of the work load (DE_84) - practitioners' (MD) knowledge on new genetic testing technologies (ES_58) - lack of new specialisations in healthcare (biologists, biotechnologists, bioinformaticians) (ES_58) - lack of translation from research to clinical applications (ES_76) - lack of training of health professionals (ES_10) - lack of knowledge about the population and patients (ES_10)	- medical doctors in general (IT_44) - research hospitals (IT_69) - communicating via guidelines (DE_32) - availability of personalised data as a basis for making decision on personalised diagnosis and treatment (DE_34) - smooth and seamless cooperation between physicians and their medical knowledge and data science (DE_37) - regulations for innovation in PM and protocols in hospitals (NL_68) - dissemination of patient centered approaches, opportunities for rare disease treatment, availability of big data for real-world evidence methodologies (IT_19) - data used to generate evidence and to make clinical decisions (quality, availability, level of impartiality) (IT_56) - lack of confidence (clarity of simulation models, repeatability, sensitivity, accuracy, etc.) (IT_56)

Table 2. *Cont.*

Key Stakeholders of the Implementation Barriers	Barriers to the Implementation of PM Interventions	Facilitators of the Implementation of PM Interventions (Ułatwienie)
Healthcare systems	- lack of common ontologies/dictionaries (IT_8) - lack of an integrated and digitalised information and data management system (ES_10), (GR_52), (IT_8), (PL_48), (DE_39) - lack of data availability and a guarantee of data security (DE_34), (DE_70), (IT_74), (SE_46) - lack of organisations well prepared to tackle PM (PT_18), (GR_52) - lack of PM in the daily provision of healthcare and in the public system (PL_7), (IT_13), (DE_70) - lack of incentives from the public system (PL_7) - lack of PM literacy and trained healthcare providers (ES_40), (GR_52) - translation into the healthcare system (DE_39) - lack of integration of health systems (GR_52), (SE_46) - transition to the PM system can cause dissatisfaction in patients with limited access to certain treatments considered not suitable for them (GR_27) - the fragmented medical system (DE_2) - PM needs a close interaction of Dx with PM Rx (DE_37) - lack of integration of patient related factors such as age, social background, etc. (DE_39) - system change if PM is implemented on a large scale (DE_2) - proof of concept for PM approaches (CH_DE) - disregarding prevention as a key component of PM (DE_45) - lack of investments (FR_82) - bureaucracy (IT_11) - lack of tools and approaches in medical practice (DE_2) - lack of demonstration projects and pilots (DE_70) - existing therapies are not yet personalised (DE_37) - insufficient socio-economic demonstration of value (FR_82) - aiming to contain the costs by health administrators (RO_42) - excessive focus on technology (PT_18)	- ethical issues around data privacy/ownership (DE_37) - public health care system in general (IT_28)
Healthcare providers	- lack of awareness and evidence of the benefits of PM (which is key to its large-scale adoption) (IT_49) - introducing radically new ways of dealing with health and treating diseases requires time (IT_49) - lack of awareness of PM approaches of healthcare providers (DE_70) - lack of a clear vision of what PM is (from only genomic medicine to the whole picture, including exposure/environmental/behavioural factors). (DE_16) - organisation of healthcare in general (FR_82) - dialogue between stakeholders (IT_53)	- direct contact with patients and better explanation of the benefits of a PM treatment by healthcare providers (IT_13)

Table 2. *Cont.*

Key Stakeholders of the Implementation Barriers	Barriers to the Implementation of PM Interventions	Facilitators of the Implementation of PM Interventions (Ułatwienie)
Patients and patient organisations	- lack of health literacy (DE_62) - lack of knowledge about available options (DE_62) - lack of public demand for PM (DE_62) - access to PM in the public system (PL_7), (DE_51) - skills of elderly people (IT_11) - concerns about the privacy of data (DE_2) - lack of public awareness (IT_15), (DE_2), (GR_52), (LV_23) - lack of PM literacy among citizens (ES_40), (ES_25) - lack of familiarisation with technology (GR_52) - lack of user-friendly PM applications (GR_52) - PM concept difficult to understand (IT_54), (IT_57), (GB_80), (DE_16) - health literacy, general literacy (IT_15) - patients as PM users should provide their experience (DE_84) - fear of sharing a large amount of personal information with healthcare providers and the industry, GDPR (IT_4), (IT_19), (FE_5) - failure to popularise the patient's responsibility for their own health and its management; too little incentive for the patient to strengthen their responsibility their health (PL_48) - involvement of patients in PM-related decisions and discussions is far too late and too little, often offered only as a last resort (DE_45) - low education in the field of PM (ES_25)	- patients' associations that can represent the patients and citizens (ES_40), (IT_64) - patients' charities and organisations, funding agencies (GB_75) - involvement (on a larger scale) of patient associations (DE_2) - education and discussion on the concept of citizens' personal health (DE_2) - positive patients' attitude (PL_22) - PM users can contribute to the dissemination of the concept and their personal experience (GR_27) - acceptance of personal data usage (DE_37) - proximity of patients and health care professionals and patient organisations, patient empowerment (ES_76) - willingness to use PM (TR_21) - communication and informing citizens of the benefits of PM (EE + 35)
Medical sector, scientific community, researchers, stakeholders	- lack of dialogue between stakeholders (IT_53) - concerns about the meaning for the relationship between patients and doctors, communication between doctors and patients (DE_2) - psychological hurdles for cross-sector innovation collaboration (healthcare, industry, government, citizen/patient). (SE_46) - lack of education of doctors and patients (DE_2), (BE_33), (IT_71), (IT_72), (ES_63) - low level of awareness among both practitioners and patients (UA_31), (DE_78), (IT_13) - lack of trust (DE_2) - education in general (PL_7) - lack of research, issues with recruitment of participants for PM clinical trials (BE_33), (ES_25) - lack of validation in diverse populations (GB_75) - lack of data sharing across academia (GB_75) - lack of willingness to introduce changes and to see advantages for practitioners and/or the patients (IT_57) - insufficient published data (DE_32) - lack of people with skills and knowledge (EU_18)	- the doctors and the informed patients (RO_42) - local molecular tumour conferences (DE_20) - digital platforms with data (DE_20) - need for individualised diagnostics and therapies (DE_39)

Table 2. *Cont.*

Key Stakeholders of the Implementation Barriers	Barriers to the Implementation of PM Interventions	Facilitators of the Implementation of PM Interventions (Ułatwienie)
Industry	- lack of infrastructure (DE_2) - lack of standardised genomic data collection (IT_28) - lack of data sharing across industry (GB_75), (IT_28) - lack of infrastructure and homogenised regulations available to enable stakeholders to provide PM services (DE_16) - lack of a clear vision of what PM is (from only genomic medicine to the whole picture, including exposure/environmental/behavioural factors) (DE_16) - lack of therapies which are actually personalised at a sufficient scale (still a lot of blockbuster mentality and business models in the pharmaceutical industry) (DE_37) - transition to PM will require shutting down existing production infrastructure and building a new one from scratch (IT_4) - lack of PM strategies and business models at pharmaceutical companies (DE_37) - the medical industrial complex relies on revenues and profits from the existing mode of operation (DK_14) - PM needs a close interaction of Dx with PM Rx (DE_37) - lack of decision-making using the genomic data on an individual level (DE_37) - industry looking for lowest costs (DE_24) - investments in general (FR_82) - lack of will of the industry to make investments before reaching certainty of their repayment (IT_4) - lack of harmonisation between policymakers, healthcare systems, end users (IT_72)	- availability of big data for real-world evidence methodologies (IT_19) - business model consideration in conflict with classic pharmaceutical business (DE_37)
Technology developers	- lack of user-friendly technology (IT_19) - technology assessment (IT_56) - lack of algorithms and structured architecture for PM and an easy user interface (TR_21) - lack of system linking electronic patient records collected by individual doctors/medical facilities (IT system) (PL_48)	- technological centres (bridging the gap for new developments) (ES_50) - technology assessment (IT_56) - artificial intelligence technologies (IT_19) - digital platforms with data (DE_20) - technology in general (DE_38) - ICT development, lower price of technologies (IT_11)
Financial institutions	- lack of funding, lack of proper reimbursement schemes/models (LT_1), (DE_73), (IT_56), (LV_23), (KZ_6), (IT_44), (DE_20), (DE_2), (IT_4), (DE_70), (IT_47), (DE_84), (PL_22), (UA_85), (IT_19) - cost of therapies & related NHS sustainability (IT_36) - time for diagnostics/therapy validation vs. costs (IT_36) - health insurance (seeking low costs) (DE_24) - cost for health care system and society (DE_66), (ES_40) - authorities and health funds fear rising costs for PM today and not gaining the promised cost reductions in the future (DE_83) - lack of financing for start-ups, for risky and ambitious projects and, in general, for R&D (DE_24) - the economic evaluation (GR_27)	

Table 2. *Cont.*

Key Stakeholders of the Implementation Barriers	Barriers to the Implementation of PM Interventions	Facilitators of the Implementation of PM Interventions (Ułatwienie)
	- cost–benefit studies (IT_12) - evaluation/reimbursement is seen as a must for medical digital solutions (FR_5) - lack of financial incentives for HCPs to experiment with PM solutions (FR_5) - fear of discrimination at insurance and employment levels (ES_25) - economic healthcare system difficulties (financial burden, lack of insurance support (ES_25), (BE_33)	- reimbursement policy definition (IT_56) - centralised evaluation system and transparency between reimbursement prices of national health care systems (FR_5) - new purchasing methodologies (i.e., value-based reimbursement) (ES_58)
Media	- insufficient use of social media (IT_44)	- traditional media (TV and newspaper) (IT_44) - media campaign, including documentaries, to make the vision more accessible to the general public (DE_2)

One of the questions included in the survey concerned the need for an increasing number of trainings/conferences to introduce and present the possibility of PM (exact question—*Do you think more training/conferences should be held to introduce and show the possibility of personalised medicine? If yes, please specify the exact field*). The question was answered in the affirmative by 58 respondents, with 16 "no" responses and 5 undecided ones.

Negative responses included explanations, such as the need for greater involvement of the mass media participation because they are more effective in shaping citizens' opinions, while training and conferences tend to attract those who are already convinced and do not reach the general public [IT_49]. Responders think that the number of conferences should not be increased, but better ones, with a clear focus on the right audience, should be organised [ES_50], or whitepapers should be created for politicians [NL_68].

The undecided respondents also highlighted the need to raise awareness about PM, but they stressed that most people will agree that PM is good, but will not follow-up after the conference [DE_16], that it is difficult to reach the citizens [DE_62], that conferences and workshops are not the priority [DE_83], and that it is not the number of trainings/conferences that is the problem. It could well be stakeholders' priorities and possibilities of attending the conference/workshop [SE_46].

Responders who saw the need for increasing the number of trainings/conferences to introduce and present the option of PM believe that it is important to develop such fields as:

1. Medical data-sharing practices and medical data protection;
2. Personalised exercise prescription;
3. Telemedicine;
4. Bioinformatics, artificial intelligence, genomics, machine learning, data analysis;
5. Professionals–patients relations, professionals–health managers relations, interdisciplinary and interprofessional approaches to health, emerging specialisations needed in personalised medicine (bioengineers, bionanotechnology specialists, physics applied to health, biodata analysts);
6. Health technology assessment in PM, including the patient's perspective;
7. Oncology, internal medicine, public health, healthcare;
8. General dissemination;
9. Value-based care;
10. Paediatrics;
11. Omics and advanced diagnostic tests;
12. Health and sport;

13. Focus group working on how to transform evidence-based medicine into PM, following rational principles;
14. Benefits for the individual and the system from the thorough application of PM;
15. PM in different disease areas/specialisations, e.g., gastroenterology.

They also emphasise the need for government dialogue, which would certainly be of great value [DE_2]. They highlight the need to engage in discussion all types of stakeholders [DK_14], involving both health organisations and university experts [EU_18].

According to the respondents, it is also important to point out the successful implementation models [DE_39], provide training, and transfer the information to general practitioners, at the right time. General practitioners should be convinced. Conference concepts should enable the exchange of information between general practitioners and specialists [DE_84].

It is also important to explain the potential risks and safety of PM to citizens [IT_74].

According to respondents, there is a noticeable need for addressing training and conferences to the general public, public citizens, patient representatives and policymakers, as well as the organisation of workshops, to facilitate dialogue between public authorities/regulators/policymakers and PM clinicians/researchers [IT_41] [ES_40]. Specific training for researchers and healthcare professionals should be done in their specific health field [ES_40].

The importance of making PM user- and professional-friendly, as well as motivational and communication techniques [GR_52] are also highlighted.

5. Discussion

PM, as noted by Horgan D. et al., is an innovative way to produce better patient outcomes, by using an individualised or stratified approach to disease and treatment which is used as a replacement of a collective treatment approach to patients. Unfortunately, despite its tangible advantages, the process of introducing PM into the member states and European healthcare systems is delayed, due to the existing barriers to the adoption of this type of treatment [9].

5.1. Government and Government Agencies

European healthcare systems have inconsistent legislation and, unfortunately, working with government agencies means bureaucracy and lengthy legislative procedures [7]. PM policies and programmes also vary significantly [10].

Incorporating personalised health into existing healthcare systems is a challenge for policymakers. There is a great need to integrate personalised health into legislation. It is very important to establish regulatory frameworks to ensure cooperation and to avoid discrimination and integrate PH into existing healthcare systems. In addition, the development of regulations and standards is truly important for the regulation of the risk, defining responsibility, and protecting individuals from inequalities in personal health [11].

5.2. Medical Doctors/Practitioners

It is crucial to adapt the way patients and medical professionals communicate and work together to promote health. This is the only way to meet future expectations for high-quality, patient-centred care [7].

PM is mostly unknown in family medicine. It is misinterpreted as a holistic or integrative type of medicine [12].

5.3. Healthcare Systems

Research activity at different locations must be integrated to maximise synergies, and scientific research must be integrated with healthcare to ensure effective translation. There is also a need to harmonise scientific practices in different research sites, science and healthcare, and science, healthcare and wider society, including the ethical and regulatory frameworks, the prevailing political and cultural ethos, and patient/citizen expectations [13].

5.4. Healthcare Providers

Healthcare providers have a long way to the full realisation of the potential of PM. Efforts to integrate new PM technologies and practices are still in the early stages, and healthcare providers face many challenges and attribute this practice gap to the implementation of PM [14].

5.5. Patients

Patients need to be educated about the benefits of data-sharing [15]. Public support for the implementation of personalised medicine policies (PMPs) in routine care is important because of the high financial costs involved and the potential for diversion of resources from other services [16].

5.6. Industry

Pharmaceutical companies need economic incentives (high enough investment returns) to develop personalised drugs. Pricing and reimbursement policies become relevant and play a fundamental role in providing such returns on investments [4].

5.7. Technology Developers

The need to develop new technologies to collect and analyse data in a way that is not just linear, but integrated (understanding functioning at the system level) and dynamic (understanding the system in motion), is recognised. According to Harvey A. et al., the most important factors for developing of technologies for PM are standardisation, integration and harmonisation. The tools and all the processes for data collection and data analysis need to be standardised across research institutes [13].

5.8. Financial Institutions

PM can contribute to improving healthcare outcomes, as well as cost–savings, mainly by eliminating the administration of some medications to patients who are predicted to be non-responsive, although some of the personalised therapies may increase costs. Therefore, at the same time, the implementation of PM requires that health policymakers assess the potential value of these types of medicines in comparison to standard treatments for each individual indication and medical context, as the incremental health benefits of PM very often also require higher health budgets [4].

Importantly, appropriate founding and reimbursement models for PM are also very important to stimulate the development and adoption of these interventions if their clear clinical benefits can be demonstrated [17].

Also, public–private financing agreements and performance-based reimbursement models could also facilitate the development and adoption of PM interventions [17].

In addition, it is important to note that defining and measuring outcomes that demonstrate the value of PM to the parties involved, unfortunately, remains an obstacle to realising the full potential of outcomes-based reimbursement [17].

5.9. Media

As we can see in the paper by Hicks–Courant K. et al., in the majority of news articles PM is not clearly defined. There has also been a noticeable increase in media coverage of the benefits, rather than the risks or challenges, of PM, and reports on specific genetic tests or targeted therapies have very often appeared after their clinical utility had been established. Unfortunately, unclear information about PM in the media may contribute to patient confusion and lack of awareness [18].

Low awareness on the topic of PM in society and the lack of political support and financial investments are the main barriers. There is a clear need to broaden opportunities for critical discourse on PM, especially among policymakers. Multi-stakeholder and multi-country strategies need to be prioritised to leverage resources and expertise [10].

Some existing strategies can be implemented now (for example those which involve activities, programmes and policies, such as those related to education, awareness and patient empowerment) or can be implemented in the near future. Regrettably, some of them require stakeholders to overcome reluctance to change traditional practices and may also require a cultural change in the way medicine is approached, which is very difficult to implement [19].

As Ayers A. said, despite the challenges, PM is widely trusted to offer the best prospects for effective treatment and cure of patients with serious diseases [20].

6. Limitations of the Study

The analysis of barriers and facilitators presented in this paper may have some limitations.

The number of people who participated in the survey may be considered an insufficient sample size for statistical measurement. Our research relies on sample sizes that are commonly known as small surveys, but which can provide generalizable results at the country level.

However, to avoid collecting unreliable data, questionnaires were sent to various stakeholders in the Regions4PerMed project. These included members of the Regions4PerMed project advisory board, as well as speakers at conferences and workshops (representatives from different countries and backgrounds, such as general practitioners, representatives of funding agencies, government institutions, academics, industry, etc.) and attendees at these events (the conferences were open, so there was noticeable participation from people interested in the topics). The professional profiles of the respondents are also diverse—from researchers (scientists), entrepreneurs, scientific staff, politicians, policy advisors, project managers, to doctors, civil servants, lawyers, public health experts, public health managers, biostatisticians, public health consultants, etc.

The different age range of the respondents is also striking, so that an overview of the barriers and facilitators to PM implementation from different age perspectives could be obtained.

The content of the questionnaire can also be seen as a limitation of the survey. It is important to emphasize that the content of the survey was approved by the supervisor, a professor experienced in both qualitative and quantitative research.

7. Conclusions

Barriers to PM adoption can be identified throughout Europe. The barriers and facilitators identified in this article need to be effectively managed in health systems across Europe. There is an urgent need to remove as many barriers as possible and create as many facilitators as possible to implement PM in the European system.

The healthcare system is currently undergoing an evolution from the traditional model, a one-size-fits-all approach, to a PM paradigm. For this reason, the evolution of healthcare toward PM requires the provision of new knowledge, a greater emphasis on the patient perspective, recognition of the value of molecular pathways in managing care, the development of new infrastructures and information management processes, and the transformation of healthcare delivery to ensure access to PM technologies and services. Addressing the challenges listed requires both short-term strategies and long-term strategies that can drive systemic and cultural change [9]. There are important interactions to consider, particularly the fact that we must first build a robust health data collection infrastructure that is widely accepted by the public, and then (later) enable data-driven evidence for effective, actionable approaches. Any relevant recommendation must clearly address this issue to make a real difference.

As Ayers (2010) said, relevant stakeholders, such as pharmaceutical and biotech companies, diagnostic companies, regulators, payers and policymakers, must work together to incentivise and remove barriers to PM. This is the only way to make this goal a reality [20]. Regrettably, European healthcare systems are only partially ready for PM adoption. If PM

is to be adopted in healthcare systems, important challenges, such as Big Data integration, health literacy, reimbursement and regulatory issues still need to be addressed [21].

Supplementary Materials: The following supporting information can be downloaded at: https://www.mdpi.com/article/10.3390/jpm13020203/s1, Supplementary Materials File S1: Questionnaire "Barriers and facilitators of Personalised Medicine implementation—qualitative study under Regions4PerMed (H2020) project"

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Data Availability Statement: Restrictions apply to the availability of these data. Data was obtained from third party and are available from the authors only as anonymised version.

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Article

Personalised Medicine—Implementation to the Healthcare System in Europe (Focus Group Discussions)

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Abstract: Background: Personalized medicine (PM) is an approach based on understanding the differences between patients with the same disease and represents a change from the "one size fits all" concept. According to this concept, appropriate therapies should be selected for specific groups of patients. PM makes it possible to predict whether a particular therapy will be effective for a particular patient. PM will still have to overcome many challenges and barriers before it can be successfully implemented in healthcare systems. However, it is essential to remember that PM is not a medical revolution but an evolution. Methods: Three focus groups were conducted, to achieve the purpose of this study, which was to identify the barriers and facilitators existing to the implementation of PM and to highlight existing practices in European countries. Focus group discussions covered the areas of barriers and facilitators to the implementation of personalized medicine. Results: This section describes the results of the focus groups that covered the areas of barriers and facilitators of personalized medicine implementation. Conclusions: Personalized medicine faces many challenges and barriers before it can be successfully implemented in health systems. The translation of PM to European countries, differences in regulations, high costs of new technologies, and reimbursement are the reasons for the delay in PM implementation.

Keywords: personalized medicine; interregional cooperation; barriers; facilitators; healthcare systems

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1. Introduction

Personalized medicine (PM) is medical treatment that tailors prevention and treatment strategies for an individual patient. There is no universally accepted definition of personalized medicine.

However, in December 2015, EU Health Ministers published the following definition of PM in the Council Conclusions on Personalised Medicine for Patients: *a medical model that uses characterisation of individuals's phenotype and genotype (e.g., molecular profiling, medical imaging, lifestyle data) for tailoring the right therapeutic strategy for the right person at the right time and/or to determine predisposition to a disease and/or to enable timely and targeted prevention* [1].

Indeed, as pointed out by Suwinski et al., growing attention is being paid to personalized medicine. This represents a fundamental shift from "one size fits all" methods of treating patients with diseases or predispositions towards new approaches, such as targeted therapies, which can achieve the best outcomes in treating patients' diseases [2].

As Yeonhee Park stated, the era of personalized medicine is approaching, taking into account individual variability of genes and environment. In this era, it is crucial to consider the patients' characteristics and demonstrate clinical benefits for patients [3].

As Jorge Alberto Bernstein Iriart noted, there is increasing investment in research in personalized and precision medicine. These investments are extremely important and require a large number of resources, as PM individualizes medical practice and puts people at the center, based on genetic testing, the identification of biomarkers, and the

development of targeted drugs. However, the individualized or preclinical medicine movement is controversial and has led to significant disputes between its proponents and critics (mainly for financial reasons) [4].

The greatest cause for concern, according to Love-Koh et al., is that PM will change how some healthcare services are delivered and evaluated, even if the adoption of PM promises significant benefits. As he points out in his paper on the future of precision medicine, the lifespan of guidelines may become shorter, uncertainties in structure may increase, and new equity considerations will emerge. With the rapid increase in biomarker discovery and the advent of artificial intelligence (AI) technologies, improvements in methods and the evaluation of evidence will help achieve and maintain the goal of cost-effective healthcare. PM allows tailoring healthcare interventions to patient groups based on their disease susceptibility, diagnostic and/or prognostic information, or response to treatment [5].

One striking problem is that there has been a massive growth in data in the health sector in recent years. Some reports state that data generation in healthcare is increasing by 48% annually [6]. As Lopes-Júnior points out, the current challenge is to turn this expanded medical data collected in the health sector into clinical benefits for patients, by providing more predictive diagnoses, treatments, and personalized care to targeted individuals and populations [7].

Personalized medicine faces many challenges and barriers to being successfully implemented in healthcare systems. However, it is essential to remember that personalized medicine is not a medical revolution but an evolution. The concept of personalized medicine has been around for several decades, and the use of personalized approaches in medical treatment has steadily increased over time. The development of new technologies has accelerated the growth of personalized medicine in recent years. However, these advances are built on a foundation of scientific research and medical practice that goes back many years. In this sense, personalized medicine can be seen as an evolution of medical practice, rather than a sudden, revolutionary change. The development of personalized medicine is an ongoing process that builds on existing knowledge and technology and will continue to evolve with discoveries and the development of new technologies.

The benefits of personalized medicine are many, ranging from improving diagnostic accuracy to identifying the best treatment option for a patient based on their characteristics, to targeted therapy that increases the likelihood of successful treatments, reduces side effects, allows for better disease prevention, and most importantly, increases patient engagement, reduces healthcare costs, and also promotes research and innovation.

This paper discusses the barriers and facilitators to the implementation of personalized medicine interventions, and forms one of the outcomes of the Horizon 2020 project Regions4PerMed: "Interregional Coordination for a fast and deep Uptake of Personalised health"

2. Purpose of the Study

The purpose of the study was to identify the existing barriers and facilitators to the implementation of personalized medicine, to identify potential methods to address them, and to highlight the existing practices in European countries that work successfully to support the implementation of personalized medicine interventions.

3. Materials and Methods

3.1. Ethics Approval

This study was approved by the Bioethics Committee of the Medical University of Wroclaw under the number KB0450/2020.

3.2. Study Design

To achieve the aim of the study, three focus groups were conducted. The discussions in the focus groups were on the areas of barriers and facilitators to implementing personalized medicine.

3.3. Settings

The discussion of the online focus groups took place on the Zoom platform. The focus groups developed provided insights into people's thinking and provided a deeper understanding of the phenomenon of personalized medicine. There were three categories of participants in the online focus group: observer, moderator, and respondent. During the focus group, questions were asked about individual understandings of personalized medicine; key facilitators and barriers to public use of PM; and how these related to respondents' private opinions about the ease of adapting PM to citizens' needs.

Specification of the questions:

Question 1: What (in your opinion) is personalized medicine?

Question 2: What are the most important facilitators and barriers to public use of personalized medicine? What are the barriers/facilitation related to?

Question 3: Can personalized medicine be easily adapted to the needs of the citizens? What could be helpful?

Details of the coding method design: participants' country code, participant number (from 1 to 7), and focus group number (from 1 to 3).

3.4. Questionnaire Survey Development and Data Collection

Participants

The focus groups were conducted in three groups. The first focus group was conducted with representatives of Polish government institutions, financial institutions, representatives of patients' rights, and patients' foundations. There were 7 participants, apart from the observer and the moderator. The second group consisted of representatives of the European Commission, the Italian Ministry of Health, a scientist, and a general practitioner from Ukraine. The second focus group was attended by 4 people. The third group was held with representatives of the Saxon State Ministry of Science, Culture and Tourism and the Fondazione Regionale per la Ricerca Biomedica. Three persons participated in this meeting.

3.5. Variables

3.5.1. Quantitative Variables

The focus groups provide information on the age, gender, and nationality of the respondents.

3.5.2. Qualitative Variables

The focus groups generated empirical data on the individual experiences of respondents in relation to barriers and facilitators to the implementation of personalized medicine across Europe.

3.6. Data Sources

The presented study analyzed data from three online focus groups covering the barriers and facilitators to implementing personalized medicine. Focus groups were conducted on the following days 10 November 2022, 29 November 2022, and 12 December 2022. The focus groups lasted between 60 and 90 min. The data was collected locally on the server.

3.7. Study Size

The results of the focus groups are presented in this study.

4. Results

4.1. Descriptive Data—Focus Groups

This section describes the results of the focus groups that covered the areas of barriers and facilitators to the implementation of personalized medicine.

During the focus groups, a difference in the definition of personalized medicine became evident.

As one focus group participant pointed out, many meetings with scientists and medical professionals began with discussions about what should be called personalized medicine, precision medicine, individualized medicine, genomic medicine, etc. [BE.3.2].

The first respondent's PM definition was individualized medicine based on genetic testing and tailored health interventions, in both preventive and restorative medicine, i.e., matching the best therapy for a person based on specific genetic predispositions [PL.1.1].

The next respondent used the definition published in the Council Conclusions in December 2015. This document contains a very broad definition of personalized medicine (the definition quoted in the introduction to this article) [BE.3.2].

According to another approach, personalized medicine exists at the moment when care takes into account personal risk factors and co-morbidities and decides what is best to prescribe to patients according to their situation, economic status, etc. There are already some international guidelines that have implemented personalized care in their approaches. For example, the American Diabetes Association has already included a personalized approach in the standards for diabetes care, when deciding what medications to prescribe and what type of prevention to offer patients, depending on their cardiovascular disease or risk factor, obesity, economic status, or kidney disease [UA.1.2].

Personalized medicine, for another respondent, means that doctors and nurses in any medical facility have information about patients, such as their age, previous diseases or conditions, information about allergies, etc., and that a diagnosis is made based on this information [IT.2.3].

As already mentioned, PM is the right therapy for the right patient at the right time, in the sense of the definition used by the European Council. Another very important aspect is data-driven personalized medicine [DE.1.3].

4.1.1. Data Protection

The collection and compilation of genetic data raises several ethical issues, and there is also a risk of leaking genetic data as medical data, which has a relatively high risk. A major problem is also the compatibility of the data collected. There are a variety of local, small, medium, and large initiatives. The data collected has a different format and is defined differently. In addition, there is a lot of archival data that cannot be used due to a lack of appropriate permissions [PL.1.1].

It should be mentioned that genetic data can be used for positive purposes; if the entire genotype in addition to the blood group were recorded on the patient's account, then on this basis, with this kind of information, it would be possible to shape the entire health policy in terms of their health needs. Scientific methods could be developed to find specific correlations between certain genes and health problems. Data collection also allows for scientific analysis [PL.1.1].

However, it was pointed out that for a worldwide database (e.g., for a bone marrow donor registry), global criteria must be met. The question was also raised as to whether it would not make sense to also examine and record the genotype when collecting umbilical cord blood from infants [PL.5.1].

In addition, it was noted that, in Poland, there is a database of basic medical data linked to paramedic and emergency department systems. According to this, a paramedic arriving at a patient's home immediately knows what disease the patient has. Such databases have been checked with security services and can be expanded [PL.6.1].

4.1.2. Data Analysis

It was also noted in the focus groups that personalized targeted therapies are often used in small groups, and small patient populations in very specific situations, which consequently creates many difficulties in obtaining reliable, validated data. There is no way to scientifically validate the evaluation of the efficacy of such therapy, which can continue for years under "unscientific" conditions for commercial purposes, often to the detriment of patients [PL.7.1].

4.1.3. Government/Political Systems

One of the main problems with introducing personalized medicine to the global market is related to government at all levels (local/regional/national/European) and the government agencies responsible for the national regulatory framework and funding of national infrastructures with different responsibilities (health/education/research/innovation) [UA.1.2].

There is a need to provide measures for the population at the state and local level. It would be helpful if patients and GPs worked together with policymakers [UA.1.2].

Even though many political systems are aware of the benefits that personalized medicine can bring. For example, today people know how to store data and how to share data, it is not done because it takes time, because it requires skills that are not necessarily available, and because it requires not just a single change, but a change in the whole system [IT.2.3].

To show the decision-makers the way, it is essential to have good examples from other countries [DE.1.3].

4.1.4. Healthcare Providers

The most important factor for introducing PM into a healthcare system is evidence. There is a need to demonstrate the evidence for PM and the legitimacy of its goals, and this is the most important issue for researchers, clinicians, and policymakers. There is also a clear need for more clinical trials [IT.4.2].

There is also a psychosocial issue; training health workers to use genetic data to share information about a possible stroke or heart failure, for example. Therefore, this "soft area" of research should be considered [PL.2.1].

4.1.5. Financial Institutions

According to several respondents, cost is the most significant barrier to implementing PM. There is a fear in the minds of policymakers and funders that PM is a rich man's medicine, and it is essential to fight against this, as it blocks the implementation of PM [BE 3.2], [FR.2.2], [UA.1.2].

However, funding therapies with guaranteed benefits or government-reimbursed medicines is problematic because the patient groups targeted by these therapies are often very small. Such narrowing of patient groups often leads to medicines being given orphan drug status, resulting in very high prices for these medicines and these therapies, which are difficult for the reimbursement system to bear [PL.7.1].

In contradistinction is the view that, in the PM context, we should not necessarily just talk about a broader approach that improves population health and makes better use of resources, not necessarily saving money, but one that makes better use of and improves health. A good example is pharmacogenomics. In this field, resources and money can be better used and lives can be saved by reducing the harmful effects of drugs [BE.3.2].

There is also a financial problem related to the funding and availability of genetic testing. Such tests are expensive and complicated. In addition, the availability of geneticists and the ability to use such data are limited [PL.7.1].

4.1.6. Medical Doctors/Practitioners

One of the most important facilitators would be the implementation of an international directive and this approach in other protocols. This would enable more effective implementation of PM in medical practice [UA.1.2].

Training events need to be conducted to share knowledge with other countries. Such training should include the different tools, omics data, and possibilities [IT.4.2].

As highlighted by the interviewees, it is worth noting that policymakers are trying to make improvements to health care close to home or to territorial health care, whereas GPs focus on the person. The more data and the more technology there is, the better, but it is also crucial that health professionals have time to focus on one patient at a time [IT.2.3].

Some healthcare professionals resist change, are reluctant, and do not embrace certain aspects, at least at the moment. This may change with time and training [DE.1.3].

Another barrier to personalized medicine is the way doctors are trained today. They are very much focused on specific disease areas and there is a lack of awareness of other disciplines, which makes full adoption of personalized medicine require a comprehensive medical approach. Thus, the training of doctors is an important factor and, if adopted, could also be an important facilitator [DE.1.3].

4.1.7. Healthcare Systems

The transformation of health organizations is also important. It is not only the training of nurses and doctors that is needed, but also the training of other professional groups that can be integrated into a hospital, to additionally support the implementation of personalized medicine [IT.2.3].

One suggestion is the introduction of so-called case managers or patient companions, people who support patients in the system, especially if they have a very threatening disease. With the depth added by personalization in healthcare, there is a need for counselling for patients and the question arises whether this must be done by a doctor or whether someone with a good medical training background might be able to help or provide guidance in the system [DE.1.3].

4.1.8. Patients

One of the many noticeable barriers to implementing PM is the personal barrier [UA.1.2].

Patient involvement in research is important. Projects are and should be more patient-centered [IT.4.2].

It is important to push for patient involvement in every step of health care and research, even if the budget is not always available [IT.4.2].

The population should become aware of PM, and of the best practices that could create this. Citizens should be better educated about what is currently possible and what PM will bring to the system [DE.1.3].

4.1.9. Technological Developments

It is very important to improve digitalization. There is also a lack of health technology assessments that properly show the benefits [DE.1.3].

5. Discussion

Precision medicine is an approach to healthcare that uses personal information, including genetic, environmental, and lifestyle data, to improve disease prevention, diagnosis, and treatment. In addition to the positive potential of precision medicine, there are concerns about data sharing, patient privacy, and equal access to treatment. The enormous potential and rapid pace of innovation, combined with the expected risks and unintended consequences, make precision medicine an ideal technological area for agile governance. Using the latest technologies to improve treatments, store patient data, and track outcomes

is essential for a country to achieve its healthcare goals under changing environmental, economic, and social conditions [8].

5.1. Government/Political Systems

Translating PM to the governance of health care is an important problem, a challenge for policymakers, and a political issue. It requires regulatory efforts, such as frameworks to protect patients and citizens from discrimination based on their genetic profile. It also requires regulation and the creation of incentives for providers and funders to develop products for the medical market [9].

One problem for Europe is the cross-border sharing of patients, biological material, and technical resources. Not all legal issues for optimal cooperation have been clarified, such as the need to transport patient data and biological material across borders [10].

PM is included in national regulations, plans, or EU-MS strategies, depending on the country, in line with the recommendations of EC. Italy has been a pioneer in implementing PM in healthcare, through specific national plans for genomics in public health genomics and omics science in public health; the United Kingdom through genomics, personalized prevention, and citizen engagement; and Estonia, through innovative strategies and biobanking [11].

5.2. Data Sharing

A critical component of personalized medicine is collecting, storing, and using genomic and clinical data from patients and healthy patients. To maximize the value of this data, it is important to create a culture in the scientific, medical, and patient communities that promotes the proper sharing of genomic and clinical information [12].

In addition, when it comes to data comparability, an important question for regulators is how to regulate data sharing among different stakeholders, particularly patients, physician practices, hospital providers, pharmaceutical and clinical researchers, and health insurers. Data sharing in PM is not only relevant for health systems in one country, but also for data exchange between different countries. This issue is a challenge for high-, low-, and middle-income economies [9].

Research has shown that there is a great need for mutual recognition for medical digital solutions published in other EU Member States [13].

5.3. Education

The training of doctors is generally still very old-fashioned and focuses on reactive treatment. In order to keep up with change, the various actors within the health system need to be trained in a completely different way. Central to this is the ability to work as part of a multidisciplinary team that includes doctors, nurses, medical imaging engineers, and others who collect information from patients [14]. After all, health professionals and citizens will determine the future of PM through their involvement, participation, and interaction in policy making. Despite increasing educational strategies, certain aspects still need to be improved, in terms of accessibility, target groups, or the tools and methods used [11].

For this reason, education and discussions on the concept of personal health are necessary for a large forum of politicians and citizens. We note that there is a lack of education of physiotherapists, as well as awareness and motivation among the population [15].

5.4. Healthcare System

According to the assessment proposed in the literature, the integration of PM into national health systems should be based on six key themes: the healthcare system, governance, access, awareness, implementation, and data. The governance dimension should include both a national strategy and comprehensive dimensions of legislation; policies; and ethical, social, and legal frameworks that address personalized medicine and genetic data sharing. On a large scale, research initiatives (national research center) should also

be launched and there should be legislation for consumer testing or a code of conduct for consumers. Study groups involving all stakeholders interested in the introduction of PM should be conducted. It should also be noted that the introduction of PM into existing healthcare systems requires matching emerging new services and practices that are aligned with both national regulations and national funding systems [9].

5.5. Financing

Personalized medicine is a new discipline that is just entering the market. Therefore, knowledge about the economic importance of PM is unfortunately not yet well developed. As Kalouguina et al. note, the literature points precisely to the insufficient quantity of real-world data, i.e., the cost-effectiveness of a personalized medicine or treatment after it has been implemented in clinical practice. Of the 26 studies reviewed by the authors that mentioned economic relevance, more than 60% pointed to a lack of studies evaluating the applicability of PM. Some of the studies mentioned the problem of funding PM, but some of the articles emphasized that this is precisely because of the lack of evidence. PM needs to overcome this lack of evidence to reach its optimal potential. In the absence of clear data on the cost-effectiveness of PM, funders do not have the slightest motivation to reimburse it, as it has not been proven that PM is profitable. As funders admit, their skepticism also stems from uncertainty about the clinical benefits of drugs and PM technologies [16].

This is because the evidence currently available is scarce and quite heterogeneous in terms of its quality and the application of common rules for documentation. Therefore, it is considered insufficient for funders to offer coverage. Therefore, there is no standard of evidence, and experts navigate cost–utility and cost–effectiveness analyses with different outcomes, such as cost per quality-adjusted life-years (QALYs), cost per life-years gained, or incremental cost-effectiveness ratios [16].

PM is considered a tailor-made prevention and treatment strategy for individuals or groups, so that patients receive specific therapies that are most appropriate for them and no money is wasted on trial-and-error treatments [17].

6. Limitations of the Study

The analytical aim of the study presented in this paper may have some limitations.

A limitation of focus groups is that the moderators may tend to generalize or categorize the individual feedback into group sentiment. To prevent this, an observer participated in the focus groups, in addition to the moderator. In addition, people with a strong influence, such as the moderator and vocal group members, can influence the conversation and make it seem one-dimensional or suppress feedback from less vocal participants. To avoid this factor, the group moderator tried to moderate the conversation, so that each participant could express their opinion. To avoid this issue, three focus groups were conducted, involving government policy representatives, health care providers, insurance policy makers, patient foundation representatives, and general practitioners.

Another limitation that can be considered is the content of the questions asked in the focus groups. However, the content of the questions was approved by a supervisor, who is a professor experienced in qualitative and quantitative research.

7. Conclusions

Personalized medicine has received significant attention in the last decade, as technologies for understanding biological differences between individuals have advanced significantly [18].

As highlighted in the introduction of this article, personalized medicine still has many challenges and barriers to overcome before it can be successfully implemented in healthcare systems.

Despite its measurable benefits, the complicated process of translating PM to EU member states and European health systems is delaying its widespread adoption [19].

There are numerous potential benefits of personalized medicine, including minimizing the risk of drug toxicity, increasing the benefits of the medicines used, contributing to the balance of the healthcare system, and facilitating drug discovery and development programs [18].

Unfortunately, there are also several barriers to smooth PM implementation, such as cost [13] (the high cost of new biotechnologies can exacerbate health inequalities and become a problem for the sustainability of health services, especially in low- and middle-income countries [4]), complexity, requirements for high-quality evidence, and the need for further training, which have so far limited the clinical implementation of pharmacogenomic testing [18].

In addition, data protection regulations and differences in regulation across European countries are problematic. Issues that need clarification were also discussed, such as the regulatory requirements for evidence for pharmacogenomic testing and the need for multiple pathways and pharmacogenomic marker development [18].

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2. Oświadczenia współautorów prac

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Jako współautor pracy pt. ***eHealth and mHealth in Chronic Diseases—Identification of Barriers, Existing Solutions, and Promoters Based on a Survey of EU Stakeholders Involved in Regions4PerMed (H2020).*** oświadczam, iż mój własny wkład merytoryczny w przygotowanie, przeprowadzenie i opracowanie badań oraz przedstawienie pracy w formie publikacji stanowi: wkład w koncepcję pracy, opracowanie metodologii, ustalenie materiałów źródłowych, recenzja i redakcja pracy, nadzór nad tworzeniem pracy oraz pozyskiwanie funduszy na jej publikację. Mój udział procentowy w przygotowaniu publikacji określam jako 20%.

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.....
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Prof. dr hab. Donata Kurpas

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Jako współautor pracy pt. ***Barriers and Facilitators to the Implementation of Personalised Medicine across Europe*** oświadczam, iż mój własny wkład merytoryczny w przygotowanie, przeprowadzenie i opracowanie badań oraz przedstawienie pracy w formie publikacji stanowi: wkład w koncepcję pracy, opracowanie metodologii, ustalenie materiałów źródłowych, recenzja i redakcja pracy, nadzór nad tworzeniem pracy oraz pozyskiwanie funduszy na jej publikację. Mój udział procentowy w przygotowaniu publikacji określam jako 20%.

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