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12 MAGGIO 2022

GIORNATA INTERNAZIONALE DELL'INFERMIERE

### L'INFERMIERE È



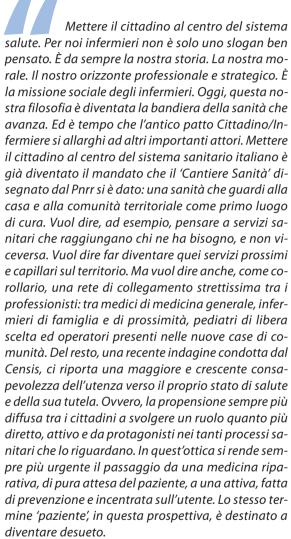
IL NOSTRO SERVIZIO SANITARIO NAZIONALE NON CRESCE





#### Infermiere, medico e paziente

### Un nuovo patto con i cittadini



Va letto soprattutto in questa ottica il cosi detto "patto di diamante". Mi riferisco all'accordo stipulato di recente tra la Federazione degli Ordini dei Medici Chirurghi e degli Odontoiatri (Fnomceo) e la Federazione degli Ordini delle Professioni infermieristiche (Fnopi). Insieme, i due organismi professionali, rappresentano quasi un milione di professionisti. Vale a dire il corpo stesso del sistema salute italiano. Un

patto scaturito dalla necessità, ma anche dalla consapevolezza, che i vecchi modelli organizzativi della sanità pre-pandemia sono logori, superati e obsoleti. E che un nuovo paradigma sanitario va scritto. Infermieri e medici sono concordi: la nuova sanità dovrà essere a misura di cittadino, con l'obiettivo di migliorare la gestione clinica della salute collettiva e dei singoli. Si tratta cioè di aprire ad altre professioni e stipulare un nuovo contratto con i cittadini: un patto medico-infermiere-paziente.

È un importante passo in avanti che le due professioni fanno insieme verso un riconoscimento reciproco dei ruoli diversi e pur complementari in seno al sistema salute. Da sempre medici e infermieri, ogni giorno e in ogni struttura sanitaria, sia pubblica che privata, fanno corpo unico per salvare vite umane e ridare salute a chi ne ha bisogno. Bisogna allora strutturare meglio questa sinergia professionale. Farla diventare strategica, fissando obiettivi di salute e organizzativi condivisi. Soprattutto sui territori, dove i problemi sanitari sono all'ordine del giorno. Come in Campania e a Napoli, in particolare. Mi riferisco alla carenza di personale. Sia nei reparti di degenza, ma soprattutto in quelli di emergenza/urgenza. È necessario colmarla per dare dignità al lavoro e migliorare l'assistenza. Ma penso anche alla formazione, per la quale è necessario trovare punti di vista integrati e condivisi. Ma soprattutto, battersi per avere più posti a disposizione per formare medici e infermieri. Non ultimo, il problema sicurezza: quotidianamente nei nostri ospedali medici e infermieri sono bersaglio privilegiato di aggressioni fisiche e verbali, senza che nessun provvedimento veramente risolutivo venga adottato. Mi piacerebbe allora che il 'patto di diamante' siglato a Roma tra le Federazioni nazionali di medici e infermieri trovasse sui territori, a partire da Napoli, le motivazioni e le sensibilità necessarie per costruire partendo dal basso quella sanità a misura di cittadino che tutti noi auspichiamo.



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#### Primo piano

6

resto gli infermieri, insieme con le altre professioni sanitarie, avranno nelle Aziende ospedaliere, nelle Asl, negli Ircs, e nelle aziende ospedaliere universitarie, dei loro specifici dirigenti. Con la nota a firma del direttore Generale Antonio Postiglione, che ringrazio personalmente, è stata accolta una nostra richiesta che riteniamo strategica e importante per offrire un servizio sanitario regionale adeguato alle richieste e alle esigenze dei cittadini, specie sul fronte della sanità territoriale e di prossimità. Naturalmente, il primo grazie va al Presidente Vincenzo De Luca per aver mantenuto l'impegno preso con gli infermieri, per aver colmato un gap sanitario e legislativo lungo 20 anni e per aver valorizzato al massimo, con questo provvedimento tutto centrato sul Piano nazionale di ripresa e resilienza, il ruolo centrale degli infermieri, individuati come i protagonisti della sanità del futuro. Poi un doveroso grazie a quanti hanno fatto propria questa battaglia a livello istituzionale. In primis la Vice presidente del Consiglio regionale, onorevole Valeria Ciarambino".

# Dirigenza professioni sa

Dopo oltre vent'anni anche in Campania passa l'applicazione della legge 251/2 Asl e Aziende ospedaliere «l'attivazione delle procedure tese al reclutamento Finalmente accolte le richieste degli infermieri». L'ASL Napoli 1 Centro deli graduatoria di merito del concorso pubblico per la copertura di 1 posto di dirig

di Pino de



Un primo step - Commentò così Teresa Rea, Presidente dell'Ordine delle professioni infermieristiche di Napoli, la nota a firma del Direttore generale del dipartimento per la tutela della Salute, Antonio Postiglione con la quale poco più di un mese fa si è chiesto alle Asl, alle Aziende Ospedaliere tutte, «l'attivazione delle procedure tese al reclutamento di dirigenti delle professioni sanitarie», anche per «rafforzare - recita proprio così il



### «Più dignità ai professionisti e più salute ai nostri cittadini»

di Valeria Ciarambino

Jenti anni per un sacrosanto diritto. Venti anni perché, prima della professionalità, sia riconosciuta la di-

gnità. Venti anni di battaglie, appelli, manifestazioni. Venti anni passando per la "vetrina", maledetta, di una pandemia che ha mostrato a tutti noi i volti di tanti eroi invisibili. Volti di chi non avrebbe avuto certo bisogno di un'emergenza di questa portata, per lasciar comprendere cosa significhi sacrificarsi notte e giorno per salvare vite umane. Volti segnati da notti insonni, dalle mascherine, da una stanchezza che non li ha mai piegati. Tutelare chi sta in prima linea per garantire il diritto alla salute è sempre stato per me un dovere imprescindibile. Ora, dopo venti anni, possiamo rivendicare un risultato storico. Le professioni infermieristiche, ostetriche, tecnico-sanitarie, della riabilitazione e della prevenzione avranno finalmente, anche in Campania, loro dirigenti all'interno delle Aziende ospedaliere e sanitarie.

Un obiettivo raggiunto in seguito a una mozione a mia firma, ap-

provata all'unanimità dall'aula del Consiglio regionale, che rivendico con orgoglio e che impegna la Regione a dare attuazione alla legge che istituisce le dirigenze per queste professioni. Una legge di ben venti anni fa. Ora dobbiamo impegnarci perché sia mantenuto l'impegno preso. Nei giorni successivi all'approvazione della mia mozione, su mia sollecitazione, il Direttore Generale Antonio Postiglione ha sollecitato tutte le Asl e le Aziende Ospedaliere a darvi attuazione. I primi effetti li stiamo già registrando. Alla Asl Napoli 1 stanno già provvedendo allo scorrimento della graduatoria, dalla Asl Caserta è partito il bando, altre aziende si stanno adoperando da settimane nella stessa direzione.

Ma bisogna far presto. Garantire una dirigenza per le professioni sanitarie equivale a migliorare l'organizzazione e, dunque, la qualità dell'assistenza ai cittadini. Al contempo, viene finalmente riconosciuta autonomia a professionisti straordinari che, specie negli ultimi anni, hanno conseguito alti livelli di formazione universitaria e post universitaria, acquisendo competenze specialistiche e manageriali. Il diritto alla salute si salvaguarda tutelando chi lo garantisce. Ed è per loro, per chi ogni giorno sta in prima linea, che continuerò a battermi senza sosta. Questo risultato è solo il primo passo.

#### Primo piano

# nitarie, ok dalla Regione

000. Con la nota a firma del direttore Generale Antonio Postiglione si chiede ad di dirigenti delle professioni sanitarie». La Presidente Rea: «Una pietra miliare. bera una convenzione con l'Aorn Santobono/Pausilipon per l'utilizzo della ente delle Professioni infermieristiche indetto dallo stesso ospedale pediatrico

#### MARTINO



testo della Regione - l'assistenza territoriale, attraverso il potenziamento delle strutture e dei presidi territoriali a gestione infermieristica»

Colmato un gap - Un passaggio importante quest'ultimo, giustamente sottolineato dalla Presidente Rea: "Si tratta di un importante riconoscimento per gli infermieri in Campania. Con questa indicazione - osserva la Rea - Non solo si fa giustizia di vent'anni di ritardo nell'applicazione della legge istitutiva della dirigenza infermieristica e delle professioni sanitarie. Ma si indica chiaramente il ruolo strategico e fondamentale che gli infermieri dovranno rivestire in futuro, gestendo in prima persona Ospedali e case della comunità. Vale a dire quei presidi territo-

### Alla dottoressa Rosaria Parmigiano la direzione del Servizio Infermieristico Asl Napoli 1 Centro

Con delibera n.1022 del 1 giugno 2022, il direttore generale dell'Asl Napoli 1, l'ingegner Ciro Verdoliva ha nominato la dottoressa Rosaria Parmigiano direttrice del Servizio Infermieristico dell'Asl Napoli 1 Centro. Si è data così un decisa accelerata alla nota a firma del direttore Generale Antonio Postiglione con la quale si è chiesto ad Asl e Aziende ospedaliere «l'attivazione delle procedure per il reclutamento di dirigenti delle professioni sanitarie». Per formalizzare l'"incarico, con esecuzione immediata, alla Napoli 1 è stata utilizzata la graduatoria del concorso per titoli ed esami per la copertura a tempo indeterminato di 1 unità



Dottoressa Rosaria Parmigiano

di Dirigente delle Professioni Infermieristiche e della Professione di Ostetrica dell'Aorn Santobono/Pausilipon. Alla dottoressa Parmigiano le felicitazioni e gli auguri di buon lavoro da parte del Consiglio direttivo dell'Ordine delle professioni infermieristiche di Napoli e delle Commissioni d'Albo. Per la Presidente Teresa Rea "la nomina della dottoressa Rosaria Parmigiano sottolinea il criterio meritocratico con cui l'Asl Napoli 1 seleziona il gruppo dirigente aziendale e il mio grazie al direttore Verdoliva va visto anche in questo senso. Alla dottoressa Parmigiano le felicitazioni mie personali e del gruppo dirigente dell'Opi Napoli e gli auguri per un proficuo lavoro".

riali a bassa intensità di cure ritenuti fondamentali dallo stesso ministro della Salute Roberto Speranza per la sanità del futuro, per un'assistenza sanitaria di prossimità che intercetti le esigenze del cittadino e dia respiro ai reparti di emergenza/urgenza degli ospedali fin troppo intasati". In effetti, nella premessa del documento firmato dal direttore Generale Antonio Postiglione si fa esplicito riferimento al Pnrr, al necessario potenziamento dell'assistenza territoriale e al piano triennale del fabbisogno del personale (Ptfp) per il quale, si dice esplicitamente nella circolare, "si ritiene necessario" procedere "all'attivazione delle procedure per il reclutamento di dirigenti delle professioni sanitarie, anche in considerazione delle sfide che ci attendono per l'immediato futuro, a cominciare dal Pnrr che prevede nella missione 6 le reti di prossimità, innovazione e ricerca, finalizzate a rafforzare la gestione territoriale attraverso il potenziamento, e la creazione di strutture e presidi territoriali a gestione infermieristica".

Detto fatto - Passa meno di un mese e l'ordinanza della Regione viene puntualmente applicata. E' l'Asl napoli 1 Centro a dare il buon esempio. Con delibera n 992 del 30 maggio scorso, il direttore Generale firmava la deliberazione per una convenzione tra l'Asl e l'Aorn Santobono/Pausilipon per l'utilizzo della graduatoria di merito del concorso pubblico per la copertura di 1 posto di dirigente della Professioni infermieristiche indetto dallo stesso ospedale pediatrico. «Apprendiamo con viva soddisfazione il varo della convenzione tra l'Asl Napoli 1 Centro e l'Aorn Santobono/Pausilipon per la copertura di 1 posto di Dirigente delle professioni infermieristiche», commenta a stretto giro la Presidente Rea. E aggiunge: «Desidero ringraziare personalmente il direttore Ciro Verdoliva per la tempestività con cui l'Asl Napoli 1 ha dato attuazione alle disposizioni regionali in materia di dirigenza delle professioni sanitarie. Questa convenzione deve considerarsi come una pietra miliare sulla strada della piena applicazione anche in Campania della legge sulla dirigenza infermieristica e delle professioni sanitarie varata ben oltre vent'anni fa. Auspichiamo - conclude la Rea - che altri direttori generali di aziende sanitarie e ospedaliere vogliano seguire ben presto il felice esempio, applicando quanto prima quanto disposto dall'autorità regionale».



#### Speciale Congresso Fnopi

n autentico successo la tappa campana del Congresso nazionale itinerante della Fnopi. Sia per i tanti infermieri presenti, sia per gli ospiti, il primo fra tutti il presidente della Regione Vincenzo De Luca, sia per i temi trattati.

I TEMI - Tre richieste, tre punti qualificanti, tre gap da colmare. Dal Belvedere di San Leucio, dove si è fermata l'ottava tappa del Congresso itinerante della Fnopi, gli infermieri, con la presidente Mangiacavalli in prima fila, lanciano il loro appello alle istituzioni e all'autorità Regionale della Campania: 1) realizzare una vera assistenza sul territorio, la cui assenza penalizza oggi non solo i professionisti, ma soprattutto gli assistiti: 2) valorizzare la professione, sia prevedendo per gli infermieri ruoli dirigenziali soprattutto per le strutture assistenziali, ma anche docenze per la formazione: gli infermieri devono formare e dirigere gli infermieri; 3) colmare la carenza di personale che in Campania sfiora le 10.000 unità (ne mancano in media il 25% di quelli che sarebbero necessari), soprattutto per realizzare le strutture previste dal PNRR, ma anche per poter assistere al meglio i cittadini: l' adeguamento degli organici garantisce assistenza in modo appropriato sia nei contesti ospedalieri, sia in quelli territoriali. Oggi l'assistenza è un'impresa difficile (soprattutto sul territorio) e chi ne fa le spese maggiori sono proprio i pazienti se sono lasciato soli e non hanno un professionista a cui rivolgersi.

**DE LUCA** – La sfilza di richieste è indirizzata ovviamente al Presidente della Re-



# Congresso Fnopi: "Più foi

Tappa campana del Congresso itinerante della Fnopi. Riuniti a San Leuc regionali e comunali. Collegamento in streeming con il Presidente d pandemia – ha detto – e per guesto dobbiamo dare impulso



gione Campania Vincenzo De Luca. Collegato in videoconferenza con la sala del congresso, per fare il punto sulle necessità reali dell'assistenza, il Governatore ha esordito con un plauso alla professione accolto dagli applausi. "Senza gli infermieri non ce l'avremmo fatta a superare la pandemia ha detto – e per questo dobbiamo dare impulso alla professione: negli ultimi due anni abbiamo impegnato 3.600 infermieri in più, di cui 900 sono stati già stabilizzati e gli altri lo saranno entro fine 2022. Poi nei nostri programmi ce ne sono almeno altri 3mila da assumere per rendere le Case della Comunità, gli Ospedali di comunità e le centrali operative previste dal PNRR efficienti ed efficaci per le persone, sul territorio". "Siamo impegnati – ha detto ancora – nella qualificazione dell'assistenza perché sia di grande qualità e per questo le tre parole che caratterizzano la professione infermieristica dovranno essere assunzioni, stabilizzazioni e formazione, perché gli infermieri acquisiscano quel ruolo di priorità che il nuovo modello di sanità ha disegnato per loro. Certo, è aperta la battaglia con Governo per avere le risorse necessarie a migliorare, la sanità perché i criteri di riparto del fondo sanitario non vanno più e ce ne vogliono di nuovi che consentano a tutti i cittadini di avere a disposizione le stesse risorse: la Campania in questo senso sta perdendo almeno 300 milioni ogni anno".

MANGIACAVALLI - "Quella dell'infermiere è la professione del futuro – ha sottolineato Barbara Mangiacavalli, presidente FNOPI – e lo è con maggiori responsabilità, formazione, specializzazioni e infungibilità della professione. Ma c'è carenza, e non solo in Campania: il rapporto infermieriabitanti in Italia è di 5,5-5,6 infermieri ogni mille abitanti contro una media dei Paesi dell'Organizzazione di 8,5, uno dei più bassi d'Europa secondo l'Ocse e il rapporto infermieri-medici, che dovrebbe essere secondo standard internazionali 1:3 è, sempre secondo l'Ocse, inferiore di 1:1,5. Secondo questi numeri di infermieri nel nostro Paese

Speciale Congresso Fnopi



# rmazione, più organici, più territorio"

io i vertici nazionali e degli ordini provinciali. Presenti il Sindaco di Caserta Carlo Marino e tanti consiglieri ella Regione Campania Vincenzo De Luca: "Senza gli infermieri non ce l'avremmo fatta a superare la alla professione". Mangiacavalli: "C'è bisogno di più formazione, più organici e più territorio"

#### di Pino de Martino

per adeguarsi almeno alla media Ocse ne mancherebbero ben oltre 100mila". "L'infermiere – spiega – assicura il buon andamento delle strutture anche evitando eventuali carenze o atti impropri di altre figure, ma deve essere supportato da un organico numericamente e professionalmente efficiente e dotazioni all'altezza di un'assistenza di qualità, altrimenti c'è il rischio di peggiorare la situazione e trasformare chi dovrebbe organizzare in un capro espiatorio



di errori altrui. Gli studi internazionale parlano chiaro: più ci si allontanata da un rapporto di un infermiere ogni 6 assistiti più aumenta il rischio di mortalità, fino a raggiungere anche il 30% di aumento. E in Italia la media è a 11, ma in Molise si raggiungono i 13 e in Campania i 17-18". "Ora – conclude la presidente FNOPI – tra PNRR, legge di Bilancio e PON che stanzia risorse proprio per il Sud la strada è aperta e non si potrà più ignorare questa esigenza".

#### LA SCHEDA

### Campania: mancano oltre 9mila infermieri

La Campania è tra le regioni quella più colpita da piani di rientro e commissariamenti negli ultimi dieci anni e dove la necessità di riequilibrare i conti si è fatta sentire pesantemente sul personale. Tra il 2009 e il 2019, il personale si è ridotto del 21% e anche in questo caso le maggiori perdite in valori assoluti si hanno tra gli infermieri (oltre 3.600 unità in meno, ma in questa Regione soprattutto uomini), gli operatori del ruolo tecnico (-2.727 unità) e i medici (-1.633). Ma la capacità formativa degli Atenei regionali non raggiunge nemmeno la possibilità di iscrivere ai corsi 900 infermieri l'anno (comunque disponibili a non meno di un triennio dall'iscrizione, con la necessità quindi, di misure urgenti e immediate). E anche per questo, gli infermieri dipendenti della Regione sono in media i più "anziani" d'Italia con quasi 55 anni medi per dipendente, contro i 45 sempre medi degli iscritti all'albo in Campania (un divario quindi di circa 10 anni) e una media nazionale rispettivamente di 51 anni e 46 (e un divario medio di 5 anni circa).

Non va meglio dal punto di vista retributivo. Il blocco dei contratti, per razionalizzare la spesa, ha fatto aumentare in dieci anni le retribuzioni solo grazie a vari automatismi, ma il potere di acquisto non ce l'ha fatta a tenere gli stipendi 2019 al livello di quelli 2009. In Campania, gli aumenti per gli infermieri nel periodo considerato sono di 299 euro lordi, ma crollano a -3.750 considerando il potere di acquisto. E si parla comunque di stipendi medi che non vanno oltre i 1.600 euro al mese considerando anche la gran mole di straordinari che sono stati necessari in carenza di personale per coprire al meglio i servizi e confermando le buste paga italiane tra le più basse d'Europa.

Quanti infermieri ci vorrebbero? Secondo le stime della FNOPI, in Campania – che è la terza Regione italiana per grandezza e abitanti – si va dai circa 7.000 pre-pandemia e PNRR ai circa 9.500 (di cui circa 2.300-2.500 infermieri di famiglia e comunità) secondo il nuovo modello di assistenza: la salute e i nuovi servizi, ma soprattutto l'assistenza sul territorio, hanno bisogno di infermieri.

La carenza porta anche a un altro dato più allarmante: secondo studi internazionali quando in media si ha un infermiere ogni 6 assistiti il rischio di mortalità scende del 30%, ma l'Italia è sulla media di 11 e la Campania, in particolare, arriva intorno ai 18, il triplo cioè dello standard indicato come ottimale.



Speciale Congresso Fnopi

# Premiate le buone pratiche

La Presidente Barbara Mangiacavalli: In Campania eccellenze in cinque province

el corso della giornata sono state premiate una serie di bestpractice infermieristiche che hanno consentito, nonostante tutto, di tenere alta l'asticella dell'assistenza anche durante la pandemia da covid-19. La stessa Presidente Barbara Mangiacavalli ha sottolineato l'impegno e la professionalità degli infermieri campani. "Forse per la prima volta in questo tour abbiamo potuto premiare cinque eccellenze, una per ogni provincia".

### NAPOLI - I primi mille giorni di vita: l'esperienza di *Home Visiting*

La ASL Napoli 3 Sud, con il Piano regionale della Prevenzione 2014-2018 ha preso in carico la responsabilità della salute dei primi mille giorni di vita del bambino, realizzando un Piano assistenziale a 360 gradi che parte dal concepimento ai primi due anni di vita e coinvolge anche il nucleo familiare. Il progetto ha come obiettivo la promozione delle competenze genitoriali e dei contesti di accudimento, il rinforzo della relazione madre-bambino e l'integrazione tra i servizi socio-sanitari territoriali nell'area materno-infantile. Attraverso un approccio *life course*, il servizio di *Home Visiting* prevede l'intervento al domicilio di un gruppo di infermiere pediatriche e ostetriche, un intervento dedicato alle donne gravide e/o delle neo-mamme residenti o domiciliate nel territorio della Asl Napoli 3 Sud, per supportarle e assisterle.

#### Salerno - Gli ambulatori infermieristici distrettuali.

L'ASL di Salerno ha attivato nel 2020 una concreta politica di sviluppo dei Servizi Sanitari Territoriali e di diversificazione dell'assistenza sanitaria, attraverso la sperimentazione e l'adozione di nuovi modelli organizzativi come gli ambulatori infermieristici territoriali, in grado di rispondere alle complesse esigenze sanitarie della cittadinanza. L'esperienza nei suoi primi mesi ha evidenziato come gli infermieri nell'assistenza infermieristica ambulatoriale siano in grado di farsi carico della salute dei cittadini, di incanalare e ottimizzare le risorse disponibili, per "sostenere" i cittadini stessi e di orientarli all'uso e all'accesso appropriato dei servizi sanitari: oltre 3.200 prestazioni infermieristiche e circa 300 pazienti cronici presi in carico nell' arco di pochi mesi. La riorganizzazione e lo sviluppo dei servizi territoriali a partire dalla creazione della rete degli ambulatori infermieristici hanno consentito all'Azienda di avviare una concreta politica di riorientamento della domanda.

### Caserta - Gli ambulatori territoriali dedicati alla Cronicità.

Con i Chronic Care Center (CCC) distribuiti su tutto il territorio provinciale, l'ASL di Caserta ha affermato il cambio di paradigma nell'assistenza alle patologie croniche Sul territorio. Il paziente incontra nei CCC un team multidisciplinare composto da specialisti e infermieri di famiglia che effettuano tutte le valutazioni di primo livello. Il team si avvale di una piattaforma clinica informatizzata in grado di incrociare i PDTA e gli stadi di avanzamento di patologia del paziente e di creare un piano assistenziale di cura individualizzato. Il ruolo dell'infermiere è fondamentale: il case management, coordinando tutto il percorso del paziente e raccordando le attività interne ed esterne; la standardizzazione della valutazione infermieristica del paziente attraverso la creazione di PDTA infermieristici per patologia; l'home caring, attraverso il telemonitoraggio e in caso di necessità, l'accesso al domicilio del paziente con il supporto del team multidisciplinare e del medico del paziente.

### Avellino - Trombolisi preospedaliera nelle aree interne dell'Avellinese

In un territorio orograficamente disagiato, dove i pazienti che presentano sindrome cardiaca acuta non possono beneficiare della prestazione cardiologica tempo-dipendente, il personale del 118 si reca presso il domicilio del paziente e può effettuare l'ECG che viene teletrasmesso alla centrale presso la cardiologia dell'ospedale di riferimento per il referto in tempo reale. In caso di necessità e in assenza di controindicazioni, gli infermieri praticano il trattamento trombolitico.

### Benevento - L'Ambulatorio infermieristico diabetologico.

Si tratta di un servizio sanitario assistenziale organizzato e tenuto da infermieri esperti ed è attivato allo scopo di rispondere ai bisogni assistenziali, educativi e formativi del paziente attraverso l'erogazione di prestazioni infermieristiche. Tra le attività erogate: raccolta dei parametri vitali, educazione al corretto autocontrollo glicemico; educazione alimentare e promozione dell'attività fisica con l'utilizzo di conversation map; educazione del caregiver alla corretta somministrazione della terapia iniettiva insulinica; esecuzione di glicemie capillari; ricerca di aree di lipodistrofia da errata somministrazione insulinica.

# Territorio: pronta la riforma da 7 mld, ma è emergenza personale

Servono fino a 40mila sanitari, ma è difficile trovarli e i fondi non bastano. La Campania fa la voce grossa. Coscioni: «Il vero problema è la programmazione». E le professioni lanciano l'allarme. Mangiacavalli (Fnopi): «Mancano gli infermieri di famiglia. Dei 9.600 previsti già nel 2020 ne sono stati trovati un terzo» di Dario de Martino

i sblocca il cuore della missione Salute del Pnrr con il via libera alla riforma della Sanità del territorio che porta con sé 7 miliardi di investimenti: dopo il serrato confronto in Conferenza Stato-Regioni dove si è registrata due volte la mancata intesa per la contrarietà della Campania. Secondo altre stime, dicono i governatori, per far viaggiare questa riforma servono almeno 2,5 miliardi, quindi manca 1 miliardo. Per il presidente dell'Agenas Enrico Coscioni la parola d'ordine è programmazione: «Dovremo porci il problema di come mai siamo l'unico Paese europeo che fa durare 4-5 anni invece di tre le specializzazioni mediche e non fa lavorare anche chi è solo laureato in Medicina». Ma anche gli infermieri fanno sentire la loro voce. La presidente di Fnopi (Ordini degli infermieri) Barbara Mangiacavalli segnala come «manchino gli infermieri di famiglia da assumere, dei 9.600 previsti già nel 2020 ne sono stati trovati un terzo. C'è un problema di attrattività della professione che comincia dalle iscrizioni universitarie: bisogna lavorare su carriera e contratti più valorizzanti e nell'immediato studiare misure come la libera professione intramoenia per gli infermieri».

Le prossime tappe - Si tratta di un tassello fondamentale per far partire quelle cure vicino alla casa degli italiani che sono drammaticamente mancate nei mesi più duri della pandemia. Un traguardo, questo, atteso entro giugno secondo il calendario del Pnrr che dà il via libera alla firma sempre entro il prossimo mese dei contratti istituzionali di sviluppo tra il ministero della Salute e le singole Regioni: nei Cis che dovrebbero essere firmati tutti insieme ci sarà il cronoprogramma e il via libera ai bandi per la co-



struzione di 1.350 case di comunità (2 miliardi), 400 ospedali di comunità (1 miliardo) e 600 centrali operative (300 milioni). Ma il via libera alla riforma apre le porte anche al potenziamento di cure domiciliari (2,7 miliardi) e telemedicina (1 miliardo).

Cosa prevede il decreto - Il decreto fissa nel dettaglio per ognuna delle nuove strutture sia la tipologia di prestazioni che il numero minimo e massimo di risorse necessarie per farle lavorare. E il punto nodale è proprio qui visto che proprio secondo gli standard per la nuova Sanità territoriale servono da un minimo di 26.550 tra medici, infermieri e altri operatori sanitari a un massimo di 39.800. Il problema è doppio perchénon solo le risorse stanziate potrebbero non essere sufficienti, ma potrebbe essere complicato trovare la "materia prima" e cioè medici e infermieri da assumere visto che già oggi è scoppiata in pronto soccorso e ospedali l'emergenza carenza. Il Governo assicura che le risorse ci sono e cioè 1 miliardo stanziato dalla legge di bilancio dell'anno scorso per il territorio a cui si aggiungono i 480 milioni nel decreto 40 del 2020 per assumere 9.600 infermieri di famiglia. Ieri lo stesso ministro della Salute Roberto Speranza in un question time alla Camera ha assicurato che anche nella prossima manovra si farà uno sforzo.

La protesta delle regioni - Le Regioni però su questo fronte si lamentano: «Secondo altre stime per far viaggiare questa riforma servono almeno 2,5 miliardi, quindi manca 1 miliardo. Ma non ne facciamo un problema di cassa piuttosto di programmazione. Per questo chiediamo una attuazione graduale dei nuovi standard», spiega Raffaele Donini che è assessore alla salute dell'Emilia Romagna e coordina i colleghi delle altre Regioni. Tra l'altro proprio Donini ha scritto al presidente delle Regioni Fedriga per segnalare anche che manca la copertura di 3,8 miliardi di spese sostenute per il Covid del 2021 e ne potrebbero servire altri 4 nel 2022.

Gli investimenti sul territorio - 1.350 Case di comunità. Sono le strutture dove lavorano medici, infermieri e altri operatori per prime cure e diagnosi, in particolare per i pazienti cronici. E 400 Ospedali di comunità, che svolgeranno una funzione intermedia tra domicilio e ospedale, con la finalità di evitare ricoveri impropri e favorire dimissioni protette.

#### La Sanità vista dagli italiani

### Collaborativa, su misura e spinta dall'innovazione

ollaborativa, su misura e spinta dall'innovazione. E' questa la Sanità del futuro secondo gli italiani. Con i cittadini al centro del processo di cura, assistenza e ricerca. A dirlo è il nuovo Rapporto condotto da Censis in collaborazione con Janssen Italia sulla Sanità nel nostro Paese. La ricerca è stata realizzata nell'ambito del progetto "I Cantieri per la Sanità del Futuro", avviato nel 2021 da Censis e Janssen Italia al fine di individuare le direttrici di sviluppo della Sanità post-Covid.. La keyword del Rapporto Censis, che esprime idee, aspettative e desideri condivisi a livello sia sociale dai cittadini sia istituzionale, è per il 2022 "RInnovAzione". Si tratta di un neologismo composto da Ricerca, Innovazione, Azione e Rinnova, parole che richiamano dinamiche decisive per costruire la Sanità che massimizza il valore Salute. Secondo gli italiani, la Sanità del futuro dovrà essere sempre più paziente-centrica e su misura: il 94,3% auspica una maggiore personalizzazione di cure, con il 92,9% che si aspetta che i percorsi di cura, dal domicilio, al territorio fino agli ospedali, siano modulati sulle esigenze personali del paziente.

Cittadinanzattiva - "Mettere il paziente al centro vuol dire capovolgere l'ottica e pensare a servizi sanitari che raggiungano i cittadini, siano prossimi e capillari sul territorio, e si avvalgano della digitalizzazione come strumento per rispondere in modo veloce e personalizzato alle loro esigenze". Così Anna Lisa Mandorino, Segretaria generale di Cittadinanzattiva. "Allo stesso tempo, aggiunge Mandorino, soprattutto per i percorsi di prevenzione e di gestione delle malattie croniche, occorre che ci sia una rete di collegamento strettissima tra i professionisti, a partire da medici di medicina generale, pediatri di libera scelta ed operatori

presenti nelle nuove case di comunità: così si può vincere la sfida di rafforzare davvero l'assistenza territoriale, come previsto dal PNRR".

Cittadini protagonisti - Questo desiderio è accompagnato dalla propensione dei cittadini a svolgere un ruolo quanto più diretto e attivo nei tanti processi relativi alla propria salute, Ben 9 italiani su 10 hanno fiducia nella ricerca (92,1%). Risulta molto alta anche la percentuale di cittadini che nutrono fiducia nel Servizio sanitario della propria regione (73,2%). Un capitale che si proietta in avanti: il 61% degli italiani è convinto che nei prossimi anni grazie alle lezioni apprese dalla pandemia la nostra Sanità migliorerà.

Le sfide del futuro - Una Sanità che dovrà farsi trovare pronta non solo a possibili nuove emergenze, ma anche alle implacabili previsioni sociodemografiche del nostro Paese: dall'evoluzione delle forme familiari con il calo della propensione a fare figli e il decollo delle famiglie unipersonali, all'allungamento della speranza di vita con il conseguente invecchiamento della popolazione e la moltiplicazione di patologie invalidanti e cronicità, che generano alti fabbisogni sociosanitari e di assistenza. In quest'ottica si rende sempre più necessario il passaggio da una medicina riparativa, di pura attesa del paziente, a una attiva di prevenzione incentrata sul paziente, che può avvenire solo in un ecosistema a organizzazione efficiente e flessibile, basato sull'innovazione e volto alla massimizzazione del valore per gli utenti, adattando ogni procedura, organizzazione, modello di governance a quell'obiettivo.



### De Luca: no all'intesa e ricorso al Tar contro il Governo

Nella Conferenza Stato-Regioni salta l'accordo sul riparto del fondo sanitario. La delegazione campana: «Criteri da rivedere». Il Governatore denuncia: «Campania derubata di 220 mln l'anno. In Italia c'e`un blocco di potere tra Veneto, Emilia e Lombardia». Diffida e ricorso al Tar Lazio per i ministri della Salute, dell'Economia e per il Governo

di Dario de Martino

iamo di fronte al tentativo di accentuare il divario fra Nord e Sud. Altro che solidarietà nazionale. Faremo la guerra». Spiega così il Governatore della Campania il mancato accordo sul riparto dei fondi destinati alla sanità per il 2022. La delegazione del presidente Vincenzo De Luca ha già depositato una diffida formale al ministero della Salute. Ed è già partito un ricorso al Tar del Lazio contro il ministero della Salute, il ministero dell'Economia e il governo. «Il ministero della Salute, d'intesa con il ministero dell'Economia non ha mai approvato i criteri per il riparto del fondo nazionale sanitario, perché in Italia c'è un blocco di potere trasversale creato da Veneto, Emilia e Lombardia». Lo ha detto il governatore Vincenzo De Luca solo qualche giorno dopo il mancato accordo sul riparto. Non ci sarà dunque nessun accordo al ribasso sulla quota che spetta alla Campania, né saranno accettate perequazioni rispetto ai tagli subiti dalla Campania per avere la popolazione più giovane d'Italia.

I criteri - Il solo peso attribuito alla popolazione anziana residente è un criterio iniquo che penalizza la Campania per circa 220 milioni di euro annui. Da venti anni risulta in effetti ultima nel riparto del budget annuo «Attenderemo che il Ministero proponga un decreto con i nuovi criteri e pesi per il riparto del fondo sanitario», dicono i componenti della delegazione campana. Da oltre dieci anni si reclama al ministero di rivedere i criteri di riparto, dando valore non solo all'età anagrafica, ma pesando anche l'entità di popolazione residente, la frequenza dei consumi per età, il tasso di mortalità e l'aspettativa di vita, per la quale la Campania è ultima in Italia. Criteri adottati dalla stessa Organizzazione mondiale della Sanità con il concetto di «povertà relativa» e di «deprivazione sociale» oltre ad altri indicatori epidemiologici che fanno riferimento ad esempio all'incidenza di malattie come diabete, obesità infantile, disabilità e altre patologie ad alto impatto sociale.

Piatto ricco – A disposizione del fondo nazionale ci sono quest'anno ben 124 mld, di cui 117 dovranno essere suddivisi tra le varie Regioni. Due in più del 2021. Un bel gruzzolo. Il che spiega anche lo strepito di spade pronte alla battaglia. «Faremo la guerra», ha annunciato non a caso il presidente De Luca appena terminata la riunione della Conferenza Stato Regioni.

«Faremo la guerra perché siamo alla

vio-

<sup>1 a</sup> **66** Faremo la guerra perché siamo alla violazione della Costituzione fondo sanitario nazionale. "Non è più tollerabile che la Campania sia la regione che riceve ad oggi la quota più bassa pro capite di risorse del fondo sanitario nazionale. E' uno scandalo. La Campania viene derubata ogni anno di 220 milioni di euro sul Fondo sanitario nazionale e abbiamo fatto una diffida formale al ministero della Salute. Non va in crisi il bilancio regionale per 200 milioni di euro, ma non sono neanche una cifra banale".

Lotta continua - Per De Luca "dobbiamo combattere con le unghie e con i denti e spesso in una condizione di totale solitudine, ma la battaglia va fatta perché è una battaglia di civiltà. Se non le facciamo, possiamo parlare di Nord e Sud ma alla fine contempleremo la nostra inesistenza".



# Visite specialistiche La prenotazione è on-line



ampania in salute» e il portale «sinfonia.regione.campania.it» saranno il mezzo virtuale per la prenotazione on line delle visite mediche specialistiche. Oltre alla tradizionale prenotazione tramite il Cup (Centro unico prenotazione), i cittadini campani hanno a disposizione anche un'applicazione informatica con la quale prenotare via web visite specialistiche o accertamenti diagnostici in strutture pubbliche. Il sistema restituisce la data della prenotazione con le informazioni relative alla ricetta medica che classifica le visite come urgenti, di media urgenza, differibili o programmabili.

Le urgenti vengono fissate in 48 ore. «In un anno e mezzo vogliamo essere la Regione più sburocratizzata d'Italia», ha detto il Presidente della Regione Campania Vincenzo De Luca. Insieme a lui Ettore Cinque, assessore al Bilancio, Antonio Postiglione, dirigente della Direzione Generale per la Tutela della salute e il Coordinamento del Sistema Sanitario regionale, Massimo Bisogno, dirigente dell'Ufficio Speciale per la crescita e la transizione digitale e Roberta Santaniello, dirigente dell'Ufficio di Diretta Collaborazione del Presidente «Governo del territorio». «Lavoriamo sulla sburocratizzazione e la semplificazione delle procedure amministrative - ha spiegato

De Luca - abbiamo cominciato con un nuovo servizio on line che consente di avere un rapporto estremamente fluido e rapido con il sistema sanitario». A dare i numeri della nuova app «Campania in salute», è stato poi il dirigente Massimo Bisogno. Si parla di decine di migliaia di campani già registrati, e di migliaia di prenotazioni effettuate, più dall'app, poco meno dal portale. «Siamo pronti a esten-

dere il servizio - ha sottolineato l'assessore Cinque - anche ai privati che hanno servizi pubblici. È un progetto mastodontico che ci porta ad avere un governo più attento dell'offerta e di un settore nevralgico lasciato un po' troppo ad agire in piena libertà. Chi fa la prenotazione su app o si presenta al Cup finisce nella stessa lista di appuntamenti, in maniera uguale».



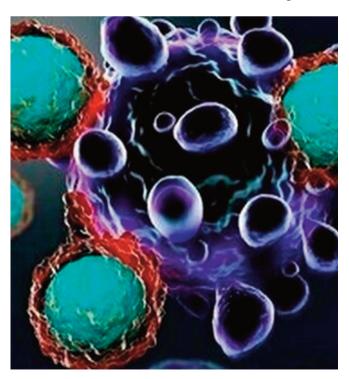
# Un vaccino universale anticancro La Campania punta sulla ricerca

Un investimento da 120 milioni. Coordinati dall'Istituto Pascale lavorano al progetto centri di ricerca universitari pubblici e privati, laboratori, aziende farmaceutiche

di Peppe Papa

a Regione Campania vuole produrre il vaccino anticancro». Lo ha deciso quattro anni fa. Dopo un ponderato consulto con i più fidati consiglieri nel ramo salute, il Governatore chiese di avviare una linea di ricerca per produrre, in Campania, il vaccino contro il cancro. «Abbiamo fatto un investimento immenso e lungimirante, 120 milioni di euro, che è più delle risorse di cui dispone tutto il Cnr nazionale». Lo ha annunciato lo stesso presidente De Luca nel corso della presentazione dei risultati del progetto di ricerca «Campania Oncoterapie». Combattere la resistenza tumorale: piattaforma integrata multidisciplinare per un approccio tecnologico innovativo alle oncoterapie».

Le collaborazioni - Con l'Ente Regione lavorano al progetto più istituzioni scientifiche. «Abbiamo messo insieme – puntualizza il Governatore - tutti gli istituti di ricerca universitari, coordinati dal Pascale, i centri di ricerca privati, laboratori, aziende farmaceutiche e abbiamo avviato una ricerca di base genetica e



sul piano farmacologico. Sono stati prodotti risultati importanti. Abbiamo già avuto l'individuazione di geni e di farmaci che - ha spiegato De Luca - impediscono la moltiplicazione di cellule tumorali. Adesso, dobbiamo passare alla sperimentazione clinica, cioè dobbiamo progressivamente arrivare a testare sugli esseri umani questi dati di ricerca cui siamo arrivati. Ma, l'obiettivo rimane quello di produrre in Campania il vaccino contro il cancro». «È un obiettivo ambizioso. Intendiamo rifare un grande investimento nella ricerca perché vogliamo arrivare assolutamente a questo risultato. Credo che abbiamo tutte le competenze mediche, scientifiche per arrivare, davvero, a produrre qualcosa che sarebbe un risultato straordinario per l'umanità», ha aggiunto De Luca. «Abbiamo alle spalle due anni di Covid che hanno determinato un rallentamento dell'attività in alcuni campi. Gli screening oncologici si sono quasi fermati», ha ammesso il Presidente. «Ma dobbiamo riprendere con estrema determinazione lo screening oncologico per quanto riguarda, in modo particolare, il tumore al seno, alla cervice dell'utero e al colon retto», ha aggiunto De Luca.

La prevenzione - «Faccio appello soprattutto alle donne e alle giovani donne perché si facciano prendere in carico dalle Asl e avviino lo screening programmatico per i tumori al seno», esorta il Presidente. E poi un monito ai cittadini e uno in indiretto ai responsabili di Asl e centro prenotazione. «A volte basta un poco di attenzione per evitare problemi seri, se si interviene per tempo. Poi, dobbiamo registrare i tempi di prenotazione per le indagini di laboratorio. Abbiamo realizzato un centro unico di prenotazione regionale, proprio per mettere in condizione il cittadino di sapere dove c'è un posto libero per andare a fare un'indagine. Le prestazioni di laboratorio sono classificate come urgenti, come programmabili e quant'altro. Le prestazioni urgenti devono essere erogate nel giro di pochi giorni. Mi viene detto che, in tante realtà, non è così. Quelle urgenti vanno erogate in pochissimi giorni. Abbiamo deciso di avviare un controllo rigoroso, Asl per Asl, ospedale per ospedale, per vedere qual è il tempo di erogazione del servizio in base alla richiesta di prestazione. Sono alcuni dei problemi che, quotidianamente, dobbiamo affrontare. Ma, dobbiamo arrivare all'obiettivo di fare della nostra sanità, come abbiamo fatto con il Covid, una sanità di assoluta eccellenza nazionale».



#### GIORNATA INTERNAZIONALE DELL'INFERMIERE

### "Portiamo la salute e la

L'Opi Napoli ha celebrato la giornata mondiale dedicata alla professione infermieristica promuovendo la pr giornata al rapporto con il territorio". Tra le autorità presenti, il Direttore generale dell'Asl Napoli 1 Ciro

di Pino de

ure e assistenza infermieristica di prossimità, per una sanità più vicina anche fisicamente al cittadino, più efficace, più efficiente, più veloce e più attenta alla prevenzione. Sono questi i temi scelti dall'Ordine delle professioni infermieristiche di Napoli in occasione della Giornata Internazionale dell'Infermiere. Abbiamo scelto di portare la salute sul territorio, in attesa che Case e Ospedali di Comunità, infermiere di famiglia e di quartiere, infermieri nelle scuole e in farmacia, diventino una realtà anche a Napoli, contribuendo a decongestionare i Pronto Soccorso ospedalieri, ingolfati da codici bianchi e verdi trattabili anche in ambulatori. Quell'assistenza territoriale che si è rivelata il tallone d'Achille del Paese al cospetto della pandemia da Covid-19". Così ha spiegato alla stampa la Presidente Opi Napoli, Teresa Rea illustrando l'iniziativa. "Con quattro stand dedicati - aggiunge - abbiamo trascorso l'intera giornata tra la gente per fare prevenzione, informazione e apprendistato sanitario di base: manovre salvavita, test hiv, misurazione parametri vitali, accessi vascolari, promozione dell'igiene e dell'allattamento al seno e tanta, tanta, buona sanità".

Le autorità - Molti i messaggi istituzionali a sostegno dell'iniziativa. Tra le autorità intervenute, il Direttore Generale dell'Asl Napoli 1 Ciro Verdoliva che ha colto l'occasione per annunciare l'imminente nomina di dirigenti infermieri come esplicitamente richiesto in una nota della Regione a firma del



dirigente Antonio Postiglione. "Abbiamo bandito dei concorsi per dare delle posizioni chiare e univoche di coordinamento infermieristico", ha detto subito il Direttore Verdoliva. E poi: "La professione dell'infermiere, come le altre professioni sanitarie,



#### GIORNATA INTERNAZIONALE DELL'INFERMIERE



# prevenzione in piazza"

evenzione e il rapporto con i cittadini. Quattro stand dedicati. La Presidente Rea: "Abbiamo dedicato questa Verdoliva: "Infermieri sono fondamenta di questo sistema sanitario. Presto posizioni di coordinamento"

#### MARTINO

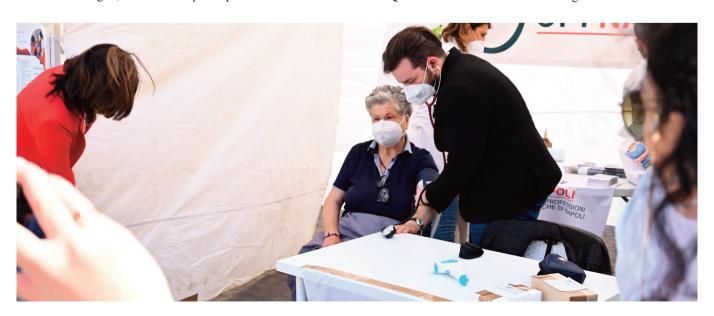


è molto importante, è alle fondamenta di questo sistema sanitario. Professionisti preparati e competenti, con un percorso di studi universitario, hanno dimostrato il loro valore, se mai ce ne fosse stato bisogno, nel corso di questa pandemia. Sono molto



vicino e credo moltissimo – ha detto infine il Dg – nei giovani professionisti che si apprestano, dopo un percorso universitario, a mettersi al servizio dei pazienti".

Quattro stand - Sono stati tanti i giovani e i cittadini che





#### GIORNATA INTERNAZIONALE DELL'INFERMIERE

hanno chiesto informazioni, presso gli stand allestiti in piazza del Gesù, sulla professione d'infermiere. In molti hanno approfittato anche per un rapido controllo dei parametri vitali e per apprendere le manovre salvavita insegnate dagli infermieri del Cives.

STAND HIV - Presso gli stand predisposti dagli infermieri è stato possibile sottoporsi gratuitamente anche al test dell'Hiv, grazie all'impegno degli infermieri dell'associazione ANLAIDS e dell'associazione VOLA.

STAND CIVES – Gli infermieri del Cives (Coordinamento Infermieri Volontari per l'Emergenza Sanitaria), come anticipato, hanno illustrato attraverso simulazioni su manichini, le manovre salvavita per la rianimazione cardiopolmonare e per la disostruzione delle vie aree.

STAND PEDIATRICI – Le infermiere e gli infermieri pediatrici hanno dato il loro contributo promuovendo l'allattamento al seno materno e fornendo informazioni sul Babywearing (fasce marsupio porta bambini) e sui recenti casi di epatite pediatrica.

STAND OPI - Cosa fanno gli infermieri? Di cosa si occupano? Come si diventa? Quale futuro per la professione? A queste domande hanno risposto gli addetti allo stand Opi spiegando ai cittadini il ruolo e le funzioni degli infermieri nel sistema sanitario nazionale e nelle strutture private. Sempre presso lo stand Opi è stato possibile sottoporsi gratuitamente al rilevamento dei parametri vitali, a cura di Opi Giovani, settore dell'Ordine professionale che ha fornito spiegazioni anche sul funzionamento del 118, del triage e del portale regionale Campania Salute. Nel campo delle competenze specialistiche sono state illustrate le pratiche degli accessi vascolari ecoguidati. Gli infermieri dell'Associazione Anipio si sono occupati infine di prevenzione e igiene promuovendo l'accurato lavaggio delle mani, mentre le addette al "Percorso Rosa" spiegavano le attività a tutela e a difesa delle aggressioni alle donne.

# Il Ministro Speranza: "La vostra professione avrà un ruolo fondamentale nella sanità del domani"

"Mai come oggi è stata più condivisa la consapevolezza di quanto sia fondamentale il contributo che gli infermieri apportano ogni giorno al servizio Sanitario nazionale con il proprio prezioso lavoro. Una professione, la vostra, che avrà un ruolo fondamentale anche nella sanità di domani e che vogliamo valorizzare per rafforzare la nostra capacità di prestare cure e assistenza". Con queste parole il **ministro della Salute, Roberto Speranza**, ha inviato il suo augurio ai 456mila professionisti che operano in Italia. "Nella Giornata Internazionale degli Infermieri – afferma Speranza – desidero rivolgere a tutti voi il mio personale ringraziamento per l'impegno profuso nei giorni più difficili della pandemia, oltreché per il lavoro quotidiano, e rinnovare l'impegno a sostenere la vostra professione in ogni ambito della sanità pubblica.



Mangiacavalli - "E' necessario un cambio di paradigma nell'assistenza e cambiare il paradigma vuol dire investire non soltanto su un maggior livello quantitativo di infermieri, ma un maggior livello qualificativo di disciplina infermieristica che guidi tutta la filiera assistenziale, disciplina che deve rimanere propria dell'infermiere e ben salda nell'evoluzione di un infermiere clinico altamente specializzato che definisca i percorsi assistenziali erogabili", ha detto la presidente della Federazione nazionale, Barbara Mangiacavalli. "Un infermiere – ha proseguito - che governi quindi tutta la "filiera assistenziale" a lui riconducibile per rendere attuabile e completo il processo di assistenza infermieristico pianificato. La mutata epidemiologia della popolazione e le necessità contingenti legate alla salute portano necessariamente all'incremento del bisogno di assistenza che corrisponde al bisogno a cui dà prevalentemente risposta il sapere infermieristico".

OpiNapoli informa

# Bilancio consuntivo e di previsione L'assemblea approva all'unanimità

on 248 si, nessun no e nessun astenuto è stato approvato nel corso dell'assemblea tenuta presso l'Hotel dei Congressi di Castellammare di Stabia, il bilancio consuntivo dell'esercizio 2021 dell'Opi Napoli. Anche il bilancio preventivo 2022 è passato senza alcuna opposizione: 267 si, nessun no e nessuna astensione. «Abbiamo un Ordine con i conti a posto, sano dal punto vista contabile e impegnato sul piano politico a difendere e valorizzare la professione. Grazie a quanti sono oggi intervenuti e a quanti, consiglieri, dipendenti, consulenti e colleghi, ogni giorno lavorano senza risparmiarsi per questa meravigliosa famiglia professionale che mi onoro di rappresentare». Così la Presidente Teresa Rea nella sua relazione introduttiva con la quale ha tracciato un bilancio anche delle cose fatte durante il secondo anno di pandemia. La presidente ha anche ricordato che la quota associativa è rimasta inalterata nonostante i rincari generalizzati e l'aumento della quota da versare alla Federazione. Di conti in ordine hanno parlato anche il tesoriere Gennaro Sanges e il presidente dei Revisori dei conti dottor Paolo Longoni nei loro interventi tecnici.





### Defibrillatori a bordo dei taxi L'assessore ringrazia l'Opi Napoli

conosciuta in tutto il mondo per le sue bellezze ma in futuro Napoli ✓ conquisterà anche il titolo di città "cardio protetta". E un contributo a questo felice risultato lo hanno dato anche gli infermieri di Napoli. Tra i donatori di questi preziosi dispositivi elettromedicali al Comune di Napoli figura infatti anche l'Opi Napoli. Lo ha ricordato lo stesso assessore comunale alla Salute, Vincenzo Santagada, che nel ringraziare gli infermieri e gli altri donatori, non nasconde l'ambizione di «dotare ogni condominio di un defibrillatore semi automatico».

La convenzione - L'iniziativa, nata dalla convenzione stipulata tra il Comune e la Città Metropolitana di Napoli ha consentito la dotazione, attraverso l'azienda medico-sanitaria Auexde, di cinque defibrillatori semiautomatici esterni corredati da teche per renderli riconoscibili anche a distanza mentre gli altri apparecchi, per un totale di undici presidi, sono stati donati da Federfarma Napoli, dalla società Farma Morra e dall'Opi, l'Ordine per le Professioni Infermieristiche di Napoli, per l'appunto. «Tutti potranno usare i defibrillatori per salvare una vita, anche cittadini non formati potranno avvalersi delle istruzioni riportate sugli apparecchi che, in ogni caso, indicano di chiamare prima il 118 e poi procedere all'uso del presidio semi automatico» sottolinea Santagada.

I taxi - Saranno circa una decina di tassisti ad usare i dispositivi salvavita. Anche se l'obiettivo è arrivare all'allestimento completo dei parchi auto a disposizione del pubblico. «Viaggiare sicuri aggiunge valore alla città di Napoli e ai servizi che offre, per questo motivo ci siamo autotassati e non ci saranno costi

aggiuntivi per chi usufruirà dei taxi col defibrillatore a bordo» spiegano Massimiliano Pagano e Tonia Ottaviano, presidenti del consorzio Radio Taxi Partenope e radio Taxi Euro 2000 che per primi hanno aderito a "Viaggia col cuore", il progetto per i taxi "cardioprotetti".

Nei quartieri - Nel capoluogo campano, saranno allestiti defibrillatori nei quartieri cittadini. Con l'installazione dei totem contenenti gli apparecchi semi automatici, qualsiasi cittadino potrà svolgere un ruolo fondamentale salvando una vita e, allo stesso tempo, l'iniziativa servirà a promuovere e sensibilizzare la cultura del primo soccorso. Le prime installazioni sul territorio sono già partite. Riguardano undici defibrillatori ma l'obiettivo è di coprire il più possibile ogni municipalità a partire dai punti strategici con maggior traffico e affluenza turistica.



#### **OpiNapoli informa**

e Professioni Sanitarie nella salute globale dell'uomo". E' questo il tema del progetto organizzato dall'Università Federico ll di Napoli, approvato e finanziato dall'Assessorato regionale alla formazione guidato da Armida Filippelli. bando al quale per la prima volta potranno partecipare anche infermieri e infermieri pediatrici. Si tratta di uno dei sette nuovi programmi di orientamento promossi dalla Regione Campania e seguiti dall'Ateneo per finanziare 'Percorsi di Formazione volti all'Orientamento alle Professioni'in partenariato con gli Ordini professionali. Il bando competitivo Progetto Tirocini 2022-2023' è stato presentato nell'Aula Magna dell'Università degli Studi di Napoli Federico II, insieme con l'ottavo progetto di tirocinio varato e finanziato totalmente dall'Ateneo Federiciano. I percorsi formativi prevedono l'organizzazione di attività seminariali di orientamento collaborazione con esperti di aziende specializzate del settore. Per ogni Progetto, di durata 18 mesi, oltre ad un percorso formativo aperto per tutti gli studenti dell'Ateneo, saranno attivati dai 20 ai 30 tirocini extramoenia, cia-

## Anche gli infermieri nei

Per la prima volta anche gli infermieri generalisti e pediatrici nei perconella salute globale dell'uomo". La Prof. Maria Triassi: "Si tratta di uni professionisti che formiamo. Da qui potrebbe venire quella

di Pino de

scuno tra i 4 e i 6 mesi, con una indennità al tirocinante di 700 euro al mese. Nei prossimi mesi saranno individuate, mediante bandi, le strutture aziendali ospitanti e si procederà alla selezione dei tirocinanti.

I progetti - Questi i progetti della Federico II proposti dalle quattro Scuole dell'Ateneo federiciano, che sono basati su partenariati con gli Ordini professionali (Ordine degli Ingegneri, Ordine degli Architetti, Ordine delle professioni infermieristiche, Ordine dei Chimici e dei Fisici, Ordine dei Medici Veterinari, Ordine dei Geologi, Ordine dei Tecnologi Alimentari, Ordine degli Agronomi, Ordine Professionale TSRM, Ordine dei Biologi, Ordine dei Farmacisti, Ordine degli Avvocati, Ordine dei Commercialisti, Ordine dei Giornalisti, ecc.) e con partner aziendali (società di servizi, società di consulenza, studi professionali, software





house, studi medici, laboratori di analisi/medicali, imprese, e altri) con l'obiettivo di offrire agli studenti l'opportunità di svolgere tirocini aziendali volti all'orientamento alle professioni: "Imparare l'Imprenditorialità ll" (resp. Prof. Antonio Bilotta); "La Filiera della Sostenibilità Agroalimentare per l'Agenda 2030", (resp. Prof.ssa Silvia Fabbrocino), in collaborazione con l'Università del Sannio; "La Medicina Veterinaria e le Produzioni Animali in una prospettiva di One Health", (resp. Prof.ssa Maria Pia Pasolini); "Cogni-



#### OpiNapoli informa

### tirocini della Federico II

orsi formativi di orientamento alle professioni."Le Professioni Sanitarie na importante occasione di crescita e di apprendistato sul campo per buona sintesi tra formazione teorica e pratica professionale" MARTINO



Prorettrice dell'Università Federico II. Animatore del convegno e dell'intero percorso formativo, il professor Pasquale Arpaia, Direttore del CIRMIS e Responsabile della gestione economica dei Progetto.

Gli interventi - "Si tratta di una importante occasione di crescita e di apsulcampo per prendistato professionisti che formiamo. Da qui potrebbe venire quella buona sintesi tra formazione teorica e pratica professionale. E trovo proficuo lo stretto raccordo con gli ordini professionali" ha detto Maria Triassi, Presidente della Scuola di Medicina e Chirurgia. Per Armida Filippelli, Assessore alla Formazione Professionale della Regione Campania: "Come Regione Campania siamo fortemente impegnati su questi progetti con l'obiettivo di fare sistema tra soggetti e istituzioni, tra ente regionale, Università e

imprese, perché la formazione deve essere il nostro motore per crescere". Il professor Stefano Consiglio, Presidente della Scuola delle Scienze Umane e Sociali, ricorda che "la Scuola è impegnata a rafforzare le sue attività di orientamento in uscita, supportando studenti e laureati nell'ingresso sul mercato del lavoro. Il potenziamento dei tirocini è una delle misure e degli strumenti molto utili in tal senso." "Continuare le attività già finanziate in passato dalla Regione è sicuramente una soddisfazione importante per la SPSB – ha sottolineato la prof Gioconda Moscariello, Presidente della Scuola Politecnica e delle Scienze di Base -. Dà atto della qualità del lavoro svolto e stimola a migliorare orientamento in uscita e placement dei nostri ragazzi". Infine, il prof Giuseppe Cringoli, Presidente della Scuola di Agraria e di Medicina Veterinaria, ha detto: "I tirocini del Progetto e il relativo contributo economico ai tirocinanti daranno un importante impulso alle attività già programmate, non solo in aziende agricole, zootecniche e di trasformazione di grande rilievo dell'area costiera, ma anche e soprattutto in importanti realtà aziendali del settore primario delle aree interne."

tive learning by Fablab", (resp. Prof.ssa Cristina Mele); "Tirocini Formativi Corsi di Studio Scuola di Medicina e Chirurgia", (resp. Prof. Orazio Scafati Taglialatela); "Le Professioni Sanitarie nella salute globale dell'uomo", (resp. Prof. Giulia Frisso); «LE.F.T.IN. – Legami Formativi Territoriali Interdisciplinari", (resp. Prof. Gianluca Luise); "Innovare, Specializzare, Intraprendere", (resp. Prof.ssa Anna Maria Zaccaria).

La presentazione – L'incontro è stato aperto dai saluti di Rita Mastrullo,





l trattamento chirurgico del reflusso gastro - esofageo (RGE) negli ultimi 30 anni ha conosciuto un'importate evoluzione. L'efficacia del trattamento medico, associato alle sequele e alle complicanze osservate anche in chirurgia laparoscopica, ha portato ad una riduzione delle indicazioni chirurgiche. D'altra parte, una più approfondita conoscenza dei meccanismi fisiologici alla base della continenza cardiale, ha permesso di perfezionare interventi antireflusso al passo con le più recenti acquisizioni fisiologiche. In ogni caso, laddove indicazioni rigorose(ernie iatale paraesofagea,ernia iatale con reflusso sintomatico, esofago di Barrett, esofagiti II-III grado) il perfezionamento della tecnica laparoscopica, ha permesso alla chirurgia mini-invasiva di diventare il gold-standard anche nel trattamento delle malattie RGE, raggiungendo casistiche superiori al 90%. I pazienti canditati all'intervento di fundoplicatio eseguono una serie di esami tra i quali ricordiamo la esogagogastroduodenoscopia, un Rx con bario del primo tratto digestivo, una manometria esofagea ed una pH- metria nelle 24 ore. Qualora questa serie di indagini dimostrino una insufficienza funzionale del LES (sfintere esofageo inferiore) vi è l'indicazione all'intervento.

Il nostro centro U.O.C. di chirurgia mini-invasiva e robotica diretto dal professore Diego Cuccurullo nella A. O. dei colli presidio Monaldi di Napoli rappresenta uno dei centri pilota e di riferimento sulla chirurgia laparoscopica del giunto gastro-esofageo.

L'intervento viene effettuato in anestesia generale con tecnica mini-invasiva, mediante cinque piccole incisioni (0,5 1cm) e l'introduzione di trocars che rappresentano le vie di accesso. Attraverso i trocars vengono introdotti gli strumenti chirurgici ed un ottica collegata ad una telecamera che consente di seguire le immagini su di un monitor.



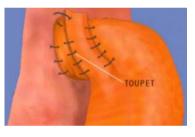
Le tecniche chirurgiche che vengono effettuate presso il nostro centro sono:

• La Fundoplicatio sec. Nissen: La tecnica chirurgica prevede la creazione con il fondo gastrico di una valva antireflusso che circonda l'esofago addominale



a 360° con punti staccati in poliestere. Inoltre si posiziona un punto staccato (sec. **Rossetti)** che fissa la parete anteriore del corpo gastrico in prossimità della valva, evitando che possa ruotare su se stessa.

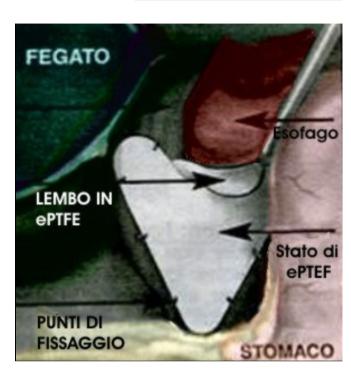
• La Gastroplastica sec. Toupet: Prevede invece la creazione con il fondo gastrico di un'emivalva antireflusso a 270° che



viene fissata sui margini destro e sinistro dell'esofago.

• La Gastroplastica sec. Dor: Essa invece si basa sulla sutura di un'emivalva anteriore del fondo gastrico a 180°ed un tipo di tecnica utilizzata in associazione all'intervento di miotomiper acalasia esofagea (disordine cronico della motilità esofagea, caratterizzato da un mancato rilasciamento dello sfintere esofageo che provoca un ostacolo al transito del bolo alimentare).

In tutte le tecniche chirugiche viene associata una mobilizzazione e plastica dei pilastri diaframmatici con punti staccati in poliestere (ethibon 2/0).in caso di difficoltà dell' iatoplastica, con sfiancamento dello iato come avviene nelle grosse ernie iatali, in passato vi era la possibilità di posizionare una protesi in PTFE (Crurasoft) fissata con spiraline in titanio o agrafes assorbibili in PDS e punti staccati in acido poliglicolico.





A distanza di anni si sono verificate complicanze con migrazioni di tale protesi ritrovate sia nel lume esofageo o gastrico, determinando la necessità di un reintervento con resezione gastrica o esofago gastrica secondo Ivor Lewis.

Oggi si preferisce utilizzare protesi riassorbibili (**BIO A**) fissate con punti e tacker riassorbibili in acido poliglicolico o PDS.



Viene posizionato un sondino naso gastrico che sarà rimosso in prima giornata. Non sono previsti drenaggi addominali. Non è necessario rimuovere i punti di sutura cutanei perché le ferite sono chiuse con sutura intradermiche riassorbibili e con minicerotti di accostamento (steri strip). In prima giornata può essere ripresa l'alimentazione liquida e dalla seconda giornata un'alimentazione semiliquida per consentire un progressivo adattamento funzionale fino alla ripresa dell'alimentazione normale che avviene dopo circa 6 mesi. In relazione al tipo di fundoplicatio si può avere, infatti una difficoltà nell'ingestione dei cibi soprattutto solidi, per cui è consigliabile seguire anche dopo le dimissioni una dieta secondo un accurato schema ce prevede cinque o sei pasti frazionati nella giornata e le pietanze devono essere semiliquide e tiepide.

#### **COLAZIONE**:

Latte, orzo, The, camomilla o latte di soia. Biscotti plasmon o fette biscottate a pappina. Zucchero o miele. Frullati di frutta. Yogurt. Uova a zabaione o coque

#### PRANZO E CENA:

Pastina glutinata primi mesi in brodo vegetale. Carne e pesce omogeneizzato o liofilizzato o ben macinato. Formaggi molli e freschi. Frutta premuta o frullata.

Tale dieta dovrà essere raccomandata per circa 4-6 settimane. Tali difficoltà diminuiranno nell'arco di 20-60 giorni. La dimissione avviene in genere dopo 48 ore dall' intervento con una prescrizione medica personalizzata: acidi biliari,anti H2, omepranzolo, procinetici da effettuare per un periodo breve di circa 20 giorni. Si può riprendere una normale attività lavorativa dopo una settimana ed eventualmente anche una modica attività sportiva dopo 20 giorni.

Il protocollo adottato presso il nostro centro negli interventi laparoscopici sul giunto gastro- esofageo è rappresentato da:

#### Preparazione pre-operatoria:

Controllo tricotomia, Xifo-sotto-ombelicale.

Profilassi antibiotica con cefalosporina.

Sondino nasogastrico e catetere vescicale all'occorrenza.

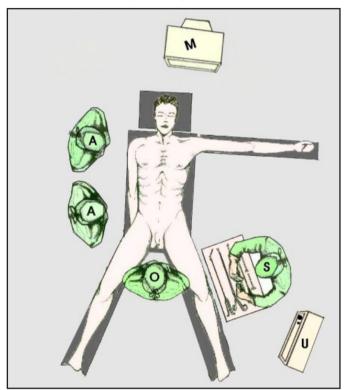
#### **Decubito:**

Supino,a gambe divaricate, in reverse-tremdeleburg di 20°-25°, lateralità dx di 30°, braccio dx lungo il corpo e braccio sx abdotto.

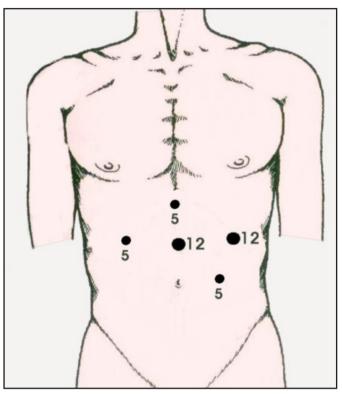
L'operatore è posto tra le gambe del paziente,il primo aiuto (telecamerista) e un assistente al lato destro del paziente infine lo strumentista alla sx del tavolo operatorio. Doppio monitor posti a livello della spalla destra e sinistra del paziente

Il I trocars 12mm è posto nel punto di mezzo tra ombelico e appendice xifoide, con tecnica **open veress assistita**, il II(5mm) è sottoxifoideo , il III 12mm è al fianco sinistro, il IV(5mm), è al fianco destro, il V(5m) in peri-ombelicale sinistra.

#### Posizione chirurghi e disposizione attrezzature:



#### Posizione dei trocars:



| Strumentario laparoscopico:  |  |                                 | Presidi:   |
|--|--|---------------------------------|--|
|  | Diametro   | Quantità                        | Cavo x elettrobisturi.   |
| Siringa con 2cc sol. fisiologica Ago di Veress Hasson Trocar Trocar Johann Grasper Delaitre (passafilo) Videoendoscopio Forbice laparoscopica - media –curva Portaghi x laparoscopia | 10-12mm<br>10-12mm<br>5mm<br>5mm<br>5mm<br>10mm<br>10mm<br>5mm | n°1 n°1 n°3 n°2 n°1 n°1 n°1 n°1 | Tubo x insufflazione. Tubo x aspirazione e irrigazione Soluzione fisiologica x irrigazione Soluzione sterile calda (ottica). Sonda luminosa con terminale sterile inter-cambiabile 50 french: (tec.Nissen) Tubo di drenaggio 14 french. Materiale sanitario: -Garze -Lunghette 15 x2,5cm |
| Cannula x aspirazione e irrigazione Divaricatore a branche multiple  | 5mm<br>5mm   | n°1<br>n°1                      |  |

| Ferri x approccio laparoscopico: |     |
|----------------------------------|-----|
| Pinza anatomica                  | n°2 |
| Pinza chirurgica                 | n°2 |
| Manico da bisturi lama11         | n°1 |
| Forbice media-curva (Metzenbaum) | n°1 |
| Forbice Mayo                     | n°1 |
| Portaghi                         | n°2 |
| Klemmer curvi                    | n°2 |
| Kocher curvi                     | n°4 |
| Divaricatore di Langebeck        | n°2 |
| Pinza x pulizia                  | n°1 |
| Coppetta                         | n°2 |
| Backhaus                         | n°8 |
|                                  |     |

#### Suturatrici metalliche: Fettuccia 18 cm Endoclip 10mm MLSutura sintetica assorbibile: (acido poliglicolico): Cal 0 ago 5/8, cal 3-0 ago ½ cerchio, ago 3/8 Sutura non assorbibile: (seta, poliestere o poliammide) Ethibond Cal.2/0 ago composite, Cal. 2/0 ago 3/8.

**Suture:** 

# Infermieri in moto ambulanze per accelerare i soccorsi

Quattro motociclette infermieristiche, tre delle quali circoleranno a Napoli ed una a Capri. È la carta che si gioca il 118 dell'Asl Napoli 1, da tempo in grave crisi di organico – mancano almeno 50 medici e 30 infermieri e rischiano di essere private del medico altre due postazioni, quella del Vomero e del Loreto Crispi – per accelerare i soccorsi relativamente a patologie da codice rosso come l'infarto e l'arresto cardiaco ed a situazioni come la presincope. Le moto sanitarie effettueranno servizio diurno, h12, dal 15 maggio al 2 agosto e saranno messe a disposizione insieme all'equipaggio dal raggruppamento temporaneo d'impresa Heart Life Croce Amica – Italy Emergenza – First Aid

One, già aggiudicatario dell'appalto per un anno per il servizio di emergenza con le ambulanze per l'importo di 4.834.305 euro. Le moto avranno per l'Asl un costo orario di 52 euro, pari a 633,72 euro al giorno. La copertura dell'intero periodo di attività richiederà un esborso di 202.790 euro per tutte e quattro le moto. Su di esse viaggeranno un soccorritore autista ed un infermiere. Nessun medico, dunque.

Accelerare gli interventi - «Il senso della operazione – dice Giuseppe Galano, direttore del 118 e presidente campano dell'associazione Anestesisti Rianimatori Ospedalieri Emer-

genza area Critica – è di arrivare con un mezzo più agile dell'ambulanza nelle situazioni nelle quali il tempo è un fattore cruciale. L'infermiere in caso di arresto cardiaco può effettuare il primo soccorso con il defibrillatore. In caso di sospetto di infarto può effettuare il cardiogramma, inviare l'esito alla centrale operativa grazie alla telemedicina e, se l'esame conferma che si tratta proprio di infarto, può, sulla base di un protocollo già attivo, somministrare i primi farmaci salvavita, sotto la guida a distanza del medico della centrale. Si guadagnano minuti preziosi in attesa che arrivi l'ambulanza per trasportare il paziente in ospedale». E aggiunge: «Anche in caso di lipotimia o di incidente

l'equipaggio della moto può effettuare i primi soccorsi». L'idea di Galano è che, se i risultati della sperimentazione saranno positivi, il servizio delle moto sanitarie possa diventare strutturale.

Ipotesi per il futuro -«In prospettiva – dice – qualora sarà risolto il problema della gravissima carenza di personale che ci attanaglia e per la quale servirebbero incentivi finalizzati a rendere attrattiva la medicina di urgenza e ad evitare fughe verso altri settori, più remunerativi e meno stressanti, si potrebbe anche pensare di far circolare motoambulanze con a bordo medici e non solo soccorritori e infermieri».



# Assistenza e pronto soccorso Un piano speciale per Procida

Un piano sanitario speciale per Procida capitale italiana della cultura. La Asl Napoli 2 riorganizza il servizio per garantire tempestività e sicurezza nell'assistenza in caso di urgenze. Si è partiti sabato 9 aprile, con la cerimonia inaugurale, alla presenza del presidente della Repubblica Sergio Mattarella e del ministro per i Beni culturali Dario Franceschini. Poi il piano speciale di emergenza urgenza che durerà per tutto il periodo delle manifestazioni e oltre andrà a regime. Per prima cosa, raddoppia la dotazione del 118, due mini-auto elettriche garantiranno un'assistenza infermieristica avanzata e affiancheranno le due autoambulanze e due auto mediche oltre che il piccolo veicolo elettrico già adibito agli spostamenti nelle stradine dell'isola.

I MEZZI - Le ambulanze avranno a bordo oltre al defibrillatore anche un innovativo massaggiatore cardiaco automatico. «Abbiamo avviato un nuovo modello di gestione del 118 - spiega il manager dell'Asl, Antonio D'Amore - utilizzando due auto elettriche di primo intervento, equipaggiate con defibrillatore e attrezzature di primo soccorso e condotte da un infermiere soccorritore



che, in collegamento coi colleghi della centrale, valuterà le condizioni del paziente e l'eventuale attivazione di ulteriori mezzi di soccorso». Sono queste dunque la novità di un modello organizzativo dei soccorsi potenziato e articolato con diversi tipi di mezzi (sono previste anche idro ambulanze e elisoccorso) e pensato per le peculiari caratteristiche di Procida.

L'OSPEDALE - Al «Gaetanina Scotto» sono stati intanto ultimati i lavori di ristrutturazione. Nell'ospedale sono disponibili tecnologie diagnostiche nuove, (Tac, elettrocardiografo, eco-

> grafo), un centro analisi e nove posti letto di tipo medico e chirurgico di cui due dedicati alla Rianimazione, una sala operatoria, una sala parto. C'è inoltre un sistema di telemedicina capace di garan

tire il consulto con specialisti di altri ospedali dell'Asl e la lettura in tempo reale di Tac e radiografie. Ancora, sono state montate attrezzature di ultima generazione per la rianimazione (ventilatori polmonari, sistemi ad alti flussi, carrelli di emergenza con defibrillatore, colonnine-monitor per i parametri vitali) che consentono di fronteggiare ogni evenienza anche legata al Covid. Non manca una nuova incubatrice adatta anche al trasporto neonatale. «Sappiamo che Procida Capitale della Cultura - continua il manager D'Amore - richiamerà sull'isola migliaia di persone. Ci siamo preparati per tempo rivedendo l'organizzazione dell'emergenza e pubblicando un bando per infermieri. Hanno risposto più di mille. A differenza di altre Asl per il 118 non abbiamo problemi di reclutamento del personale. Le auto elettriche ci permetteranno di arrivare in tempi rapidi ovunque, nonostante la folla e i vicoli stretti». Se necessario il trasporto in terraferma potrà contare sull'idro ambulanza gestita in collaborazione con la Capitaneria di Porto e sull'elisoccorso (Procida è infatti dotata di una base attrezzata per il volo notturno).



### - ampania

# Manca il personale, il Loreto Mare riapre, ma senza il pronto soccorso

Chiusa la lunga stagione di ospedale Covid, riapre il Loreto Mare di Napoli e mette a disposizione 112 posti letto, entrando a far parte dell'orbita dell'ospedale San Paolo. Questa la decisione ufficiale, dopo una serie di riunioni, dall'Asl Napoli 1 diretta da Ciro Verdoliva che gestisce i due ospedali. L'ospedale riaprirà con il nuovo assetto entro la fine di giugno. Non avrà però ancora il pronto soccorso che resta chiuso a causa, spiegano fonti della Asl, della mancanza di personale di emergenza. Resta la speranza di poter riaprire il pronto soccorso nel centro di Napoli in caso di assunzione di nuovi medici per l'emergenza.Il Loreto Mare al



momento avrà 28 posti di medicina generale 10 di oncologia, 10 di terapia intensiva, 28 per lungodegenti 20 di pediatria, 16 per l'ematologia. In particolare i 20 posti per pediatria erano stati programmati una parte all'Ospedale del Mare e il resto al San Giovanni Bosco e ora invece saranno riuniti al Loreto Mare. La nuova configurazione è stata decisa per riattivare l'ospedale dopo l'emergenza Covid.»I nuovi venti posti del Loreto Mare di pediatria sono una buona notizia per il Santobono, è importante avere una cura per i bambini nel centro di Napoli e noi siamo pronti nei collegamenti con le nuove tecnologie se servissero delle consulenze specialistiche» ha commentato Rodolfo Conenna, direttore generale dell'ospedale pediatrico Santobono di Napoli.»E' importante - spiega Conenna - che ci sia una forte assistenza pediatrica nel centro storico della città dando anche la possibilità al Santobono di essere più libero per emergenze minori. Speriamo che possano avere nel reparto una piena funzionalità prima dell'inverno quando abbiamo i picchi. Noi siamo pronti a collaborare con sistemi di telemedicina e di teleconsulto per non spostare i bambini grazie agli strumenti moderni»Il Santobono sta anche per lanciare un nuovo concorso per otto posti nell'ospedale pediatrico e la messa a punto di una lista di professionisti idonei da cui potranno attingere anche altri ospedali cittadini come il Loreto Mare.

### Tumore al colon retto. Nuova terapia al Pascale

Si allunga e migliora la qualità della vita dei pazienti affetti da tumore al colon retto metastatico. Tutto merito di una cura, che associa un anticorpo alla chemioterapia, ma che viene somministrata non più secondo posologia, ma secondo i casi. Ad intermittenza. Solo se e quando è necessario, dunque. Tutto questo significa: meno effetti collaterali, meno accessi in ospedale, migliore qualità della vita, sopravvivenza libera da malattia che si allunga a 20 mesi rispetto ai 13 del trattamento standard in quanto, nel momento in cui la cura viene interrotta, le cellule tumorali non fanno in tempo ad adattarsi al farmaco e, quindi, sviluppano più tardi la resistenza.

E' quanto emerge dallo studio «Improve», tutto italiano, coordinato dall'Istituto dei tumori di Napoli, e presentato a Chicago all'Asco, il Congresso americano di oncologia. La

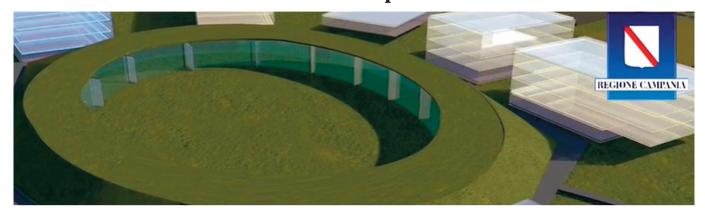


nuova strategia di somministrazione della cura avrebbe avuto effetti positivi su 137 pazienti con tumore del colon retto metastatico, in prima linea di trattamento, arruolati in 14 centri italiani.

Dai primi dati è emerso che somministrando l'anticorpo anti-EGFR panitumumab con la chemioterapia standard e confrontando la modalità classica di somministrazione continua verso una somministrazione alternata a periodi di interruzione, in questi pazienti è migliorata l'efficacia del trattamento e al tempo stesso si sono attenuati alcuni effetti collaterali, come la tossicità cutanea, che impatta in maniera significativa sulla loro qualità di vita

Lo studio ha dimostrato per la prima volta nel tumore del colon-retto che il trattamento sperimentale intermittente comporta un miglioramento della sopravvivenza libera da progressione. In particolare nei tumori del colon metastatico la sopravvivenza libera da progressione ha raggiunto i 20 mesi con un miglioramento di 7 mesi rispetto al trattamento standard.

# Nuovo Santobono a Ponticelli. Un Polo pediatrico da 300 milioni di euro



Sorgerà a Ponticelli, alla periferia di Napoli, in un'area di 85mila metri quadrati, il nuovo ospedale pediatrico Santobono. Il progetto da tempo annunciato ora ha una roadmap certa. Lo ha stabilito la conferenza di servizi che ha dato il via alla progettazione esecutiva con l'ok del presidente della giunta regionale, Vincenzo De Luca; del sindaco di Napoli, Gaetano Manfredi e del direttore generale del Santobono-Pausilipon, Rodolfo Conenna. La conferenza di servizi ha approvato la fase progettuale. E sarà una delle tre mega opere annunciate da Vincenzo De Luca per una spesa complessiva di circa due miliardi di euro: polo pediatrico Santobono a Ponticelli; il nuovo palazzo della Regione Campania che dovrebbe sorgere a ridosso di piazza Garibaldi e il nuovo ospedale di Salerno. Il via libera al progetto è stato fornito dalla conferenza dei servizi che si è riunita con il presidente della giunta regionale De Luca, il sindaco di Napoli Gaetano Manfredi, il direttore generale dell'Aorn Santobono-Pausilipon, Rodolfo Conenna e la sua struttura tecnica.

I costi - Il costo stimato del nuovo polo pediatrico sarà di 300 milioni di euro: l'ospedale Nuovo Santobono avrà una dotazione complessiva di 480 posti letto articolati in oltre 25 differenti sub specialità pediatriche medico-chirurgiche, si articolerà nelle seguenti aree funzionali:

Aree funzionali – Il Dipartimento regionale emergenza pediatrica sarà dotato di 142 posti letto ordinari, aree di assistenza intensiva e sub intensiva multispecialistiche, un complesso operatorio autonomo ed un servizio di diagnostica per immagini; l'intera area ad alto contenuto tecnologico è dedicata a soddisfare la domanda di assistenza complessa in emergenza urgenza pediatrica e neonatale per l'intero bacino regionale. L'ospedale pediatrico multispecialistico sarà dotato di 238 posti letto ordinari dedicati ad attività elettive e ultra specialistiche in fase acuta. L'area prevede un complesso operatorio autonomo attrezzato per la chirurgia robotica. La Riabilitazione intensiva e robotica riabilitativa sarà dotata di 32 posti letto post acuti; quest'area prevede un piscina e centro di recupero funzionale ad alta tecnologia ro-

botica. Il **Blocco diagnostica e laboratori di ricerca** comprenderà oltre al servizio immunostrasfusionale, ai laboratori di diagnostica clinica, HLA ed Aferesi ed alla banca di cellule staminali e di criopreservazione di cellule e tessuti, ai laboratori per la fase I, un polo avanzato di ricerca traslazionale nel settore oncologico e delle malattie rare. Inoltre, è prevista anche un'area dedicata ai servizi alla persona e alla umanizzazione con residenze per i genitori dei degenti; Asilo (figli per il personale); RSA diurno; Auditorium e mediateca; Pet terapy; Fondazione Associazioni; Shop, Emporio, edicola, Bar ristorante, Mensa dipendenti, Area relax, Area fitness per dipendenti.

De Luca - «Con un grande investimento manteniamo l'impegno che avevamo assunto come Regione per la città di Napoli. Realizzeremo, nell'area Est, un polo pediatrico di valore europeo – ha commentato il presidente De Luca - con l'obiettivo di creare il quarto polo pediatrico italiano. E, per farlo, puntiamo oltre all'alta specializzazione, anche a una architettura di qualità che arricchisca il patrimonio artistico contemporaneo della città di Napoli. D'altra parte, è provato che, quando riqualifichi un territorio, cresce anche lo spirito civico». Per il sindaco di Napoli, Gaetano Manfredi: «La soluzione individuata ci consente di poter operare in tempi rapidi e senza fare varianti al piano regolatore e si inserisce nella riqualificazione dell'area Est di Napoli. Il Comune metterà a disposizione circa 5mila metri quadrati di sua proprietà e investirà sui servizi, sulle aree verdi e sulle infrastrutture del quartiere per collegare i due poli ospedalieri con il tessuto urbano e con la città». «Con questo progetto stiamo ripensando la sanità pediatrica regionale dei prossimi 30 anni», ha infine sottolineato soddisfatto Rodolfo Conenna, direttore generale del Santobono-Pausilipon. «L'Azienda ospedaliera sta già investendo sulla ricerca e sui giovani, molti sono i professionisti che vogliono rientrare in Italia dall'estero perché attratti da questo nuovo grande progetto. Studi scientifici hanno dimostrato il potere curativo del bello, ed è per questo che il nuovo Santobono non sarà solo funzionale, ma anche architettonicamente attraente».

### Asl Napoli 1 Centro e Progetto Reumacenter: supporto psicologico per malattie reumatiche

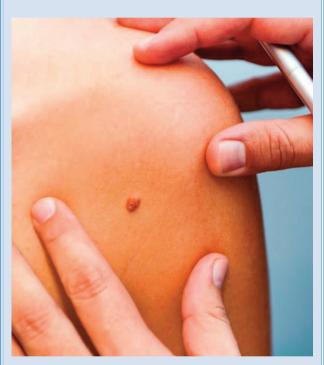
Reumacenter diventa operativo. Stiamo parlando del progetto ideato da Giuseppina Errico, psicologa Direttrice dell'Associazione Genitori per Sempre, finanziato dalla Regione Campania, in collaborazione con l'Asl Napoli 1 Centro.

Il progetto, finanziato dalla regione Campania e realizzato dall'Asl Napoli 1 Centro, prevede un affiancamento all'attività del reumatologo con il supporto psicologico per il trattamento dei pazienti affetti da malattie reumatiche, in particolar modo dalla Sindrome Fibromialgica. Ma permetterà anche ai pazienti affetti da artrite reumatoide, artrite psoriasica, spondilite anchilosante di migliorare la loro qualità di vita. Prevede infatti un percorso di cura integrato di tipo clinico, farmacologico e psicologico per il malato reumatico.

Le attività saranno realizzate in forma gratuita per 150 pazienti all'Ospedale San Giovanni Bosco, il Presidio Sanitario Intermedio Napoli Est e presso il nuovo Centro di Medicina, Psicologia e Psicoterapia Sistemica di Napoli diretto da Errico. In questa ultima sede si svolgeranno tutti i laboratori previsti dal progetto: training autogeno, medicina narrativa, musicoterapia, teatroterapia, ortoterapia e gruppi di incontro self-help. Al San Giovanni Bosco tutor del progetto è Enrico Tirri, Direttore dell'Uosd di Reumatologia, docente nella Scuola di Specializzazione di Reumatologia dell'Università degli Studi della Campania "Luigi Vanvitelli" e Consigliere Nazionale della Società Italiana di Reumatologia (Sir), al Presidio Sanitario Intermedio Napoli Est Tito d'Errico, Responsabile dell'Ambulatorio e D.H. di Reumatologia.



### Tumori della pelle: all'Ascalesi la diagnosi precoce prima in Italia



Nel cuore di Napoli, a un passo dalla stazione centrale e nell'ospedale più antico della città, c'è il sistema più moderno efficiente e innovativo per la diagnosi dei tumori della pelle. All'Ospedale Ascalesi, è già operativo (è stato inaugurato a metà aprile) Vectra WB360. Si tratta di un dispositivo con tecnologia avanzata per la diagnosi precoci dei tumori della pelle. Ed è il primo sistema di screening simultaneo di tutte le neoformazioni o lesioni del corpo, basato sia sulla visione clinica che su quella dermatoscopica o in epiluminescenza. Ovvero, una sorta di tac senza raggi X e con un sistema di telecamere, capace di individuare in pochissimi secondi, il tempo di quattro flash, tutti i nei a rischio melanoma. La diagnosi è pronta in dodici minuti, giusto il tempo di scannerizzare le immagini. L'innovativo macchinario sarà gestito presso gli ambulatori oncologici del presidio ospedaliero di Forcella che da due anni è accorpato al Pascale.

### In dialisi stando comodamente a casa Intervento pilota all'Ospedale Cardarelli

E' stato eseguito al Cardarelli il primo intervento mini-invasivo nel Mezzogiorno per la dialisi peritoneale. «Un cambio di passo decisivo che migliorerà la vita di moltissimi pazienti», ha sottolineato il manager Giuseppe Longo, spiegando che grazie a questo intervento si può continuare ad avere una vita attiva e per molti versi normale. A intervenire Olga Credendino, direttrice della Nefrologia, coadiuvata dai chirurghi Simone Squillante ed Eugenio Gragnano (quest'ultimo responsabile della week surgery). La dialisi peritoneale ha come particolarità quella di configurarsi come una terapia domiciliare, che il paziente può eseguire

a casa propria dopo un breve training svolto presso il centro dialisi di riferimento. Il meccanismo depurativo viene definito dai medici "endogeno", perché sfrutta una membrana naturale che si trova nell'addome. Questa membrana filtra il liquido dializzante introdotto nella cavità peritoneale attraverso un piccolo catetere. «La possibilità di eseguire questo intervento per via mini invasiva - commenta il direttore sanitario Giuseppe Russo - conferma l'eccellenza della nostra Azienda anche per la dialisi e le competenze chirurgiche laparoscopiche, qualificandoci come un punto di riferimento nel Mezzogiorno». In Italia la prevalenza della dialisi peritoneale è garantita al 10% circa della popolazione sottoposta a dialisi. Dai dati del registro regionale si evince che in Campania il trattamento, però, si ferma al 2 per cento circa. Su circa 5.500 pazienti, poco più di un centinaio, in pratica, viene sottoposto alla dialisi peritoneale. Una percentuale molto bassa, probabilmente a causa del fatto che l'85-90 per cento degli interventi emodialitici si effettua nei centri privati accreditati, dove la dialisi peritoneale non è autorizzata. In questo senso, e anche per questo, l'innovazione oggi proposta dal Cardarelli di Napoli determina un cambio di passo fondamentale.



# Gli screening oncologici si prenotano in farmacia

È stato siglato un protocollo d'intesa tra l'Asl Napoli 1 e Federfarma, che fornirà una nuova spinta nell'attività di educazione e di informazione sanitaria per quel che concerne il tumore della mammella, della cervice uterina e del colon-retto, neoplasie che sono le più frequenti e per questo inserite nei parametri di monitoraggio nazionali dei Livelli essenziali di assistenza. In particolare, le farmacie di comunità convenzionate proporranno ai cittadini arruolabili l'adesione



screening e prenoteranno direttamente attraverso il Cup gli appuntamenti. «Anche questa nuova iniziativa - sottolinea il direttore generale della Asl, Ciro Verdoliva - nasce con la volontà di dare seguito all'indirizzo del Presidente De Luca nell'ambito della campagna 'Mi voglio bene', messa in campo dalla Regione Cam-

pania per sostenere la prevenzione e offrire un'assistenza diagnostica tempestiva, specializzata e gratuita a donne e uomini residenti e domiciliati nelle cinque province campane». Le visite saranno calendarizzate nei Distretti sanitari di base della Asl che ha già provveduto a potenziare l'offerta. I centri sono infatti aperti dal lunedì al venerdì dalle 8.30 alle 13.00 e dalle 15.00 alle 18.00 e il sabato delle 9.00 alle 13.00. Ancor più capillare l'offerta dedicata allo screening del

tumore del colon retto. Saranno direttamente le farmacie a consegnare gratuitamente i contenitori per il sangue occulto nelle feci ai cittadini che, prelevato il campione, lo riporteranno in farmacia. A loro volta, le farmacie provvederanno a consegnare i campioni al laboratorio di riferimento dell'Asl che provvederà ad analizzarli.

### A Sant'Agata dei Goti una sezione del Pascale di Napoli

All'ospedale Sant'Alfonso de Liguori di Sant'Agata de Goti è in piena attività l'Unità Skin Cancer dell'ospedale Pascale, l'Istituto Tumori di Napoli. La struttura dell'ospedale Pascale, almeno per il momento, si occuperà soltanto delle neoplasie della pelle. All'Unità Skin Cancer è stato dedicato un intero reparto al secondo piano dell'ospedale Sant'Alfonso de Liguori di

Sant'Agata de Goti. A guidare l'attività Paolo Ascierto con una parte del suo team: il dermatologo Marco Palla, i chirurghi Corrado Caracò e Lucia Benedetto. «Abbiamo visitato i primi 30 pazienti presso questa nuova struttura che entra a tutti gli effetti a far parte del più grande polo oncologico del Mezzogiorno», ha detto il dottor Ascierto. L'obiettivo – continua l'oncologo napo-



letano – è di ridurre il gap tra richiesta e offerta ospedaliera. Vogliamo mettere la nostra competenza a servizio dei pazienti per incrementare l'accesso alle cure e ridurre i tempi di attesa rivalutando il territorio e la collaborazione tra i molteplici enti come auspicato dal decreto regionale sulla rete oncologica». L'apertura dell'Unità Skin Cancer del Pascale a Sant'Agata de Goti è stata fortemente voluta da Attilio Bianchi, direttore generale dell'Istituto Tumori di Napoli, in sinergia con Mario Ferrante, direttore dell'azienda ospedaliera San Pio di Benevento. Nell'ottica della strategia messa a punto dalla rete oncologica regionale, e quindi di andare sempre più incontro alle esigenze dei pazienti, dopo i laboratori aperti già da una quindicina di anni al Crom di Mercogliano e gli ambulatori inaugurati due anni fa all'Ascalesi, nel centro storico di Napoli, il più grande polo oncologico del Mezzogiorno si fa ora in quattro.

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# Marcianise, nuova Terapia intensiva all'ospedale 'Guerriero'



Grazie all'acquisto di moderne e sofisticate apparecchiature all'avanguardia, la terapia intensiva dell'Ospedale di Marcianise si annovera tra le più moderne e tecnologicamente avanzate di tutto Mezzogiorno d'Italia. Si tratta di un primo step nell'ampio progetto di ampliamento ed ammodernamento del Guerriero.

Punto di arrivo posto a 200 posti letto. «Come rapporto tra il numero di cittadini e la percentuale di dipendenti e posti letto nella sanità, la provincia Caserta è stata la provincia più penalizzata, rispetto ad

altri territori come Salerno. Questo squilibrio bisogna sanarlo, e noi lo stiamo facendo, ma per farlo bisogna prendere precise scelte politiche e una visione di ciò che si vuole fare - ha detto il presidente della Regione Campania Vincenzo De Luca. A Caserta abbiamo assegnato 400 milioni di euro, non solo per Marcianise ma anche per un ospedale quasi al confine della regione come Sessa Aurunca, cui abbiamo destinato 60 milioni di euro; lì non ho alcuna base elettorale, eppure lo abbiamo fatto perché era giusto farlo».

### Campania sul podio in Italia per interventi light al cuore

La pandemia non ha fermato, ma solo rallentato la sempre maggiore propensione all'utilizzo della Tavi, la tecnologia che consente di impiantare una valvola aortica trans-catetere in caso di patologie cardiovascolari molto gravi come la stenosi aortica degenerativa. Evitando cioè gli inter-



venti a cuore aperto. Negli ultimi cinque anni, infatti, il numero complessivo di interventi in Italia è quasi raddoppiato, da 4500 sa 8200. La Campania, invece, in un solo anno ha visto effettuati 797 interventi TAVI, pari al 10,5% del totale degli interventi nel nostro Paese, in aumento di circa l'1% rispetto all'anno precedente nonostante la coincidenza con il primo anno di pandemia, mentre nel resto d'Italia la riduzione è stata di circa il 70%. Un dato che ha portato la nostra Regione al terzo posto in Italia, alle spalle solo della Lombardia (in testa con ben 1674 interventi) e del Veneto (859), ma davanti ad altre realtà importanti come l'Emilia-Romagna (692) e la Toscana (621). Sono alcuni dei dati che confermano l'eccellenza della Regione in questo campo.





#### COVID-19 Vaccines Side Effects Among Iraqi people In Kurdistan Region:

#### A cross-sectional study

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**Background**: Communities around the world have expressed concern about the safety and side effects of SARS-CoV-2 vaccines. The adverse effects of the Covid-19 vaccines played a critical role in public trust in the vaccines. The current study aimed to provide evidence on the side effects of the BNT163b2 mRNA COVID-19 vaccine (Pfizer-BioNTech®); ChAdOx1 nCoV-19 vaccine (AstraZeneca®); BBIBP-CorVvaccine (Sinopharm®) COVID-19 vaccines.

Material and Methods: A cross-sectional study design was performed from April 26th, 2021, to June 3rd, 2021. Convenience sampling was used to select respondents; face validity was performed to the mandatory multiple-choice items questionnaire to cover the respondent's demographic characteristics, coronavirus-19 related anamneses, and the side effect duration of coronavirus-19 vaccines, the data were analyzed by using descriptive statistics.

**Results:** The 588 participants enrolled in the current study. ChAdOx1 nCoV-19 vaccine received 49.7%, followed by BNT163b2 mRNA COVID-19 vaccine and BBIBP-CorV (39.5% and 10.9%). The most common complaint was headache (61.2%), followed by vaccine injection site discomfort (58.8%), fatigue (49.7%), fever (48.3%), muscle discomfort (42.9%), and approximately (10.5% and 10.2%) had injection site swelling and nausea, respectively. Most of those surveyed had post-vaccine symptoms for one to two days (25.2%), (41%), and only a small percentage (3.7%) experienced them for over one month. ChAdOx1 nCoV-19 vaccine handled 53% of the side effects, followed by BNT163b2 mRNA COVID-19 vaccine (42%) and BBIBP-CorV vaccines (5%).

**Conclusion**: Prevalence of various local and systemic vaccines side effects, such as headache, fever, and pain at the injection site, was observed. Almost all participants had mild symptoms and were well-tolerated .AstraZeneca® vaccine has the most side effects, followed by the Pfizer® vaccine, and the Sinopharm® vaccine has the least. More independent studies on vaccination safety and public awareness are critical to improving public trust in vaccines.

**Keywords**: COVID-19; Vaccines; Side effects; Prevalence; Cross-sectional design.



# INTRODUCTION

Millions of people around the world were infected by the Coronavirus Disease-2019 (COVID-19) within three months, until World Health Organization declared it as a pandemic on March 11, 2020 [1]. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is a coronavirus that belongs to the Coronaviridae family's Sarbecovirus subgenus, and a non-segmented positive-sense Ribonucleic acid (RNA) virus encompasses it [2]. Older individuals are at an increased risk of being infected with the SARS-CoV-2 [3]. Most vaccine options target the spike (S) protein. It is the principal target of neutralizing antibodies. It helps to neutralize antibodies to prevent the Angiotensin Converting Enzyme-2 (ACE2) receptor binding motif (RBM) from engaging with the host cell [4, 5]. The vaccine development for COVID-19 prevention has grown into a struggle between viruses and humans, which has made it more complicated, along with the discovery of other related strains. Many platforms are attempting to grow, with Deoxyribonucleic acid (DNA) and RNA-based platform showing the most promise [6]. Several countries have entered the vaccine development battle, hastening the clinical trial phase and attempting to produce an efficient and safe vaccine against COVID-19 [7]. The COVID-19 vaccines have been studied in large, randomizedcontrolled studies with people of all ages, genders, nationalities, and individuals with known medical disorders. Across all demographics, the vaccines have shown a high level of effectiveness and are safe and efficacious in patients with various underlying diseases [8]. According to a recent national study [9], the side effects of the COVID-19 vaccine were the most common reason for vaccine hesitancy among the population in the United Kingdom (U.K.). This finding was confirmed in the context of COVID-19 vaccinations, as fear of side effects has been cited as the primary reason for healthcare workers and students in Poland refusing to accept the Covid-19 vaccine [10, 11]. Vaccines are not completely free of side effects or complications [26], headache, nausea, pain, redness, and swelling are early adverse effects of vaccines that must be expected when taking vaccines [27]. Furthermore, conditions like blood clotting were suggested to be caused by the



administration of COVID-19 vaccines from Pfizer, Moderna, and AstraZeneca. [28,29]. The present study aimed to determine the prevalence of side effects of the COVID-19 vaccine among vaccinated people in the Kurdistan Region, Iraq.

# MATERIALS AND METHODS

# Study design

The study was conducted using a cross-sectional design from April 26th to June 3rd, 2021, in the Kurdistan region, Iraq.

# Samples and sampling

An Internet-based study in the Kurdistan region of Iraq recruited to enroll a sample size of 588 people from people who had been vaccinated with one of the following vaccines: BBIBP-CorV, ChAdOx1 nCoV-19 vaccine, and BNT163b2 mRNA COVID-19 vaccines. However, illiterate and old age individuals were interviewed directly by authors to increase the sample representation. The individuals were invited by using invitation links in Viber<sup>TM</sup>, Facebook<sup>TM</sup>, and WhatsApp<sup>TM</sup> groups by using a non-random convenience sampling method. A Google<sup>TM</sup> form document was utilized to host and deliver the questions to responders. The inclusion criteria were participants who received one of the three mentioned COVID-19 vaccines and either received the first or second dose of the vaccine.

# Instruments of the study

The self-administered questionnaire of the present study, composed of nine mandatory multiple-choice items, has been adapted from previous studies and World Health Organization data [12, 13]. The questionnaire was divided into four parts: the first part included demographic data, including gender, age, and profession; the second part dealt with COVID-19 history, including COVID-19



previous infection, type and dose of COVID-9 vaccines, and medical history like having any chronic disease; the third part included the side effects and side effect duration of COVID-19 vaccines.

# **Ethics**

The present study was carried out in accordance with the Helsinki Declaration". Study approval was obtained by written authorization of the Ethics Committee of the College of Nursing at Duhok University. The approval is without a serial number and verbal informed consent has been obtained from each participant before participation in the current study.

# Statistical analysis

The descriptive statistics were performed to determine the study variables; age, gender, occupation, and the data that related to the COVID-19 vaccine. The current study used SPSS version 23 for the descriptive statistics.

# RESULTS

588 participants in the study. Nearly two-thirds of participants were males (64.3%); their mean age was 41.5 years and ranged between 18 and 65 years. Most of the participants were healthcare workers (31.3%), government employees (25.2%), jobless (19), students (18), and self-employed (6.5%), as shown in Table 1.

According to some questions stated in Table 2, nearly half (46.3%) of the participants did not infect before taking the vaccine. About (40.8%) reported that they were infected with COVID-19 previously. Compared with a tiny percentage (12.9%) having the vaccine without knowing whether they were infected with the COVID-19 virus or not.



| Demographic items   | No. | %    |  |  |  |  |  |  |
|---------------------|-----|------|--|--|--|--|--|--|
| Gender              |     |      |  |  |  |  |  |  |
| Male                | 378 | 64.3 |  |  |  |  |  |  |
| Female              | 210 | 35.7 |  |  |  |  |  |  |
| Age                 |     |      |  |  |  |  |  |  |
| 18-25               | 138 | 23.5 |  |  |  |  |  |  |
| 26-33               | 156 | 26.5 |  |  |  |  |  |  |
| 34-41               | 130 | 22.1 |  |  |  |  |  |  |
| 42-49               | 78  | 13.3 |  |  |  |  |  |  |
| 50-57               | 48  | 8.2  |  |  |  |  |  |  |
| 58-64               | 30  | 5.1  |  |  |  |  |  |  |
| 65+                 | 8   | 1.4  |  |  |  |  |  |  |
| Occupation          |     |      |  |  |  |  |  |  |
| Healthcare workers  | 184 | 31.3 |  |  |  |  |  |  |
| Government Employee | 148 | 25.2 |  |  |  |  |  |  |
| Students            | 106 | 18   |  |  |  |  |  |  |
| Self-employee       | 38  | 6.5  |  |  |  |  |  |  |
| Jobless             | 112 | 19   |  |  |  |  |  |  |
| Total               | 588 | 100  |  |  |  |  |  |  |

 Table 1. Demographic Characteristics of study participants

| Anamnesis                      |     |      |  |  |  |
|--------------------------------|-----|------|--|--|--|
| Previous COVID-19 infection    | No. | %    |  |  |  |
| Yes                            | 240 | 40.8 |  |  |  |
| No                             | 272 | 46.3 |  |  |  |
| I do not know                  | 76  | 12.9 |  |  |  |
| Chronic diseases               |     |      |  |  |  |
| Yes                            | 130 | 22.1 |  |  |  |
| No                             | 458 | 77.9 |  |  |  |
| Types of COVID-19 vaccines     |     |      |  |  |  |
| BNT163b2 mRNA COVID-19 vaccine | 232 | 39.5 |  |  |  |
| ChAdOx1 nCoV-19 vaccine        | 292 | 49.7 |  |  |  |
| BBIBP-CorV                     | 64  | 10.9 |  |  |  |
| No. of Doses                   |     |      |  |  |  |
| 1 dose                         | 466 | 79.3 |  |  |  |
| 2 doses                        | 122 | 20.7 |  |  |  |
| Total                          | 588 | 100% |  |  |  |

 Table 2. COVID-19 vaccines related anamnesis



Regarding chronic diseases among the participants who had the COVID-19 vaccine, over three-quarters (77.9%) had no chronic diseases. The most common types of vaccines received by the participants were ChAdOx1 nCoV-19 vaccine (49.7%), followed by BNT163b2 mRNA COVID-19 vaccine and BBIBP-CorV (39.5% and 10.9%). Regarding the number of vaccine doses gained, over three-quarters (79.3%) of participants had a single dose of vaccine at the time of the study.

Regarding the response of the participants toward COVID-19 side effects, they reported having at least one side effect after the COVID-19 vaccine job. The most common side effects among the study population (61.2%) were headaches, followed by vaccine injection site pain (58.8%), fatigue (49.7%), fever (48.3%), muscle pain (42.9%), and nearly the same percentage (10.5% and 10.2%) complained of injection site swelling and nausea, respectively. Rarely (0.3% and 0.7%) reported mouth ulcers and tonsillitis, side effects of the vaccine, as noted in Table 3.

| Side effects            | No. | %    |
|-------------------------|-----|------|
| Headache                | 360 | 61.2 |
| Fever                   | 284 | 48.3 |
| Injection site pain     | 346 | 58.8 |
| Nausea                  | 60  | 10.2 |
| Epigastric Pain         | 42  | 7.1  |
| Chills                  | 98  | 16.7 |
| Joint pain              | 154 | 26.2 |
| Muscles pain            | 252 | 42.9 |
| Fatigue                 | 292 | 49.7 |
| Injecting site swelling | 62  | 10.5 |
| Rash                    | 10  | 1.7  |
| Backache                | 108 | 18.4 |
| Tonsillitis             | 4   | 0.7  |
| Mouth Ulcers            | 2   | 0.3  |
| None of the above       | 58  | 9.9  |
| Total                   | 588 | 100% |

 Table 3. Prevalence of COVID-19 vaccine side effects among study participants



Table 4 shows that, for the duration of the occurrence of side effects, the vast majority (41.5%) of the participants had post-vaccination side effects for about two days, while 25.2% had them for one day, and 10.9% of the individuals complained about side effects for three days. 3.7% of them had a longer duration of side effects for over one month.

| Duration                 | No. | %     |
|--------------------------|-----|-------|
| 1 day                    | 148 | 25.2  |
| 2 days                   | 244 | 41.5  |
| 3 days                   | 64  | 10.9  |
| 4 days                   | 24  | 4.1   |
| 5 days                   | 10  | 1.7   |
| 6 days                   | 2   | 0.3   |
| 1 week                   | 8   | 1.4   |
| More than 1 week         | 2   | 0.3   |
| More than 1 Month        | 22  | 3.7   |
| No side effects duration | 64  | 10.9  |
| Total                    | 588 | 100.0 |

**Table 4**. The duration of side effects of COVID-19 vaccines

Regarding side effect prevalence with different age groups, symptoms were more common among the younger age groups ranging from 18 to 57 years old. Symptoms were much less severe in older age groups (58–64), with no noticeable side effects observed in participants older than 60 years old. Headache was more common in the age group 34-41 years old (14.2%); injection site pain was more common in the age group 26-33 years old (16.6%); fatigue was more common in the age group 34-41 years old (13.2%) as in Table 5.

Concerning the occurrence of side effects among BNT163b2 mRNA COVID-19 vaccine, ChAdOx1 nCoV-19 vaccine, and BBIBP-CorV vaccines, the vast majority (53%) of the side effects were because of ChAdOx1 nCoV-19 vaccine, followed by BNT163b2 mRNA COVID-19 vaccine (42%), BBIBP-CorV vaccines (5%) were safer than BNT163b2 mRNA COVID-19 vaccine and ChAdOx1



nCoV-19 vaccine vaccines in that almost all side effects occurred among vaccinated individuals.

| Side effects            | Age        |            |            |            |           |          |          |  |  |
|-------------------------|------------|------------|------------|------------|-----------|----------|----------|--|--|
|                         | 18-25      | 26-33      | 34-41      | 42-49      | 50-57     | 58-64    | 65+      |  |  |
| Headache                | 84 (12.2%) | 76 (12.9%) | 84 (14.2%) | 56 (9.5%)  | 40 (6.8%) | 18 (3%)  | 2 (0.3%) |  |  |
| Injecting site pain     | 64 (10.8%) | 98 (16.6%) | 88 (14.9%) | 54 (9.1%)  | 26 (4.4%) | 10(1.7%) | 6 (1%)   |  |  |
| Fever                   | 66 (11.2%) | 70 (11.9%) | 66 (11.2%) | 44 (7.4%)  | 32 (5.4%) | 4 (0.6%) | 2 (0.3%) |  |  |
| Nausea                  | 20 (3.4%)  | 12 (2%)    | 10 (1.7%)  | 8 (1.3%)   | 8 (1.3%)  | 2 (0.3%) | 0 (0%)   |  |  |
| Epigastric pain         | 14 (2.3%)  | 10 (1.7%)  | 6 (1%)     | 2 (0.3%)   | 8 (1.3%)  | 2 (0.3%) | 0 (0%)   |  |  |
| Chills                  | 22 (3.7%)  | 30 (5.1%)  | 26 (4.4%)  | 12 (2%)    | 6 (1%)    | 2 (0.3%) | 0 (0%)   |  |  |
| Fatigue                 | 58 (9.8%)  | 68 (11.5%) | 78 (13.2%) | 46 (7.8%)  | 32 (5.4%) | 6 (1%)   | 4 (0.6%) |  |  |
| Rash                    | 6 (0.6%)   | 4 (0.6%)   | 0 (0%)     | 0 (0%)     | 0 (0%)    | 0 (0%)   | 0 (0%)   |  |  |
| Joint pain              | 28 (4.7%)  | 42 (7.1%)  | 34 (5.7%)  | 28 (4.7%)  | 14 (2.3%) | 6 (1%)   | 2 (0.3%) |  |  |
| Muscle pain             | 34 (5.7%)  | 58 (9.8%)  | 72 (12.2%) | 54 (9.1%)  | 28 (4.7%) | 4 (0.6%) | 2 (0.3%) |  |  |
| Injection site swelling | 14 (2.3%)  | 20 (3.4%)  | 10 (1.7%)  | 12 (2%)    | 2 (0.3%)  | 2 (0.3%) | 4 (0.6%) |  |  |
| Backache                | 20 (3.4%)  | 36 (6.1%)  | 24 (4%)    | 16 (2.7%)  | 10 (1.7%) | 0 (0%)   | 2 (0.3%) |  |  |
| Tonsillitis             | 4 (0.6%)   | 0 (0%)     | 0 (0%)     | 0 (0%)     | 0 (0%)    | 0 (0%)   | 0 (0%)   |  |  |
| Mouth Ulcers            | 2 (0.3%)   | 0 (0%)     | 2 (0.3%)   | 0 (0%)     | 0 (0%)    | 0 (0%)   | 0 (0%)   |  |  |
| None of the above       | 18 (3%)    | 14 (2.3%)  | 14 (2.3%)  | 2 (0.3%)   | 8 (1.3%)  | 2 (0.3%) | 0 (0%)   |  |  |
| Total                   | 436(74.1%) | 524(89.1%) | 500(85%)   | 332(56.4%) | 206 (35%) | 56(9.5%) | 24 (4%)  |  |  |

**Table 5.** Prevalence of the side effects of COVID-19 vaccines among age groups

Some side effects such as nausea, epigastric pain, chills, injection site swelling, backaches, tonsillitis, and mouth ulcers have not occurred at all. Only a few participants (43.7%, 28.1%, 21.9%, and 18.7%, respectively) experienced injection site pain, fatigue, headache, and fever after receiving the BBIBP-CorV vaccine.

Most of the symptoms were observable in those who received the ChAdOx1 nCoV-19 vaccine and BNT163b2 mRNA COVID-19 vaccine vaccines, although symptoms were more common in individuals vaccinated with ChAdOx1 nCoV-19 vaccine. Common side effects between BNT163b2 mRNA COVID-19 vaccine and ChAdOx1 nCoV-19 vaccine were headache (69 % versus 63.7 %),



injection site pain (56.8 % versus 63.6 %), fever (42.2 % versus 59.5 %), fatigue (56.8 % versus 48.6%), and muscle pain (44.8 versus 47.9 %) as shown in Table 6.

|                         | Types of COVID-19 Vaccines                |                                   |                |  |  |
|-------------------------|---|-----------------------------------|----------------|--|--|
| Side effects            | BNT163b2<br>mRNA COVID-<br>19 vaccine (%) | ChAdOx1<br>nCoV-19 vaccine<br>(%) | BBIBP-CorV (%) |  |  |
|                         |   |                                   |                |  |  |
| Headache                | 160 (69%)                                 | 186 (63.7%)                       | 14 (21.9%)     |  |  |
| Injecting site pain     | 132 (56.8%)                               | 186 (63.6%)                       | 28 (43.7%)     |  |  |
| Fever                   | 98 (42.2%)                                | 174 (59.5%)                       | 12 (18.7%)     |  |  |
| Nausea                  | 34 (14.6%)                                | 26 (8.9%)                         | 0 (0%)         |  |  |
| Epigastric pain         | 24 (10.3%)                                | 18 (6.1%)                         | 0 (0%)         |  |  |
| Chills                  | 20 (8.6%)                                 | 78 (26.7%)                        | 0 (0%)         |  |  |
| Fatigue                 | 132 (56.8%)                               | 142 (48.6%)                       | 18 (28.1%)     |  |  |
| Rash                    | 2 (0.8%)                                  | 4 (1.3%)                          | 4 (6.2%)       |  |  |
| Joint pain              | 58 (25%)                                  | 94 (32.1%)                        | 2 (3.1%)       |  |  |
| Muscle pain             | 104 (44.8%)                               | 140 (47.9%)                       | 8 (12.5%)      |  |  |
| Injection site swelling | 2 (0.8%)                                  | 40 (13.6%)                        | 0 (0%)         |  |  |
| Backache                | 4 (1.7%)                                  | 68 (23.2%)                        | 0 (0%)         |  |  |
| Tonsillitis             | 4 (1.7%)                                  | 0 (0%)                            | 0 (0%)         |  |  |
| Mouth Ulcers            | 0 (0%)                                    | 2 (0.6%)                          | 0 (0%)         |  |  |
| None of the above       | 24 (10.3%)                                | 20 (6.8%)                         | 14 (21.8%)     |  |  |
| Total                   | 774 (42%)                                 | 1158 (53%)                        | 86 (5%)        |  |  |

**Table 6.** Occurrence of side effects between vaccines

# **DISCUSSION**

During the pandemic of COVID-19, the World Health Organization recommended that all nations strive to maintain population immunization. Although legislation and policies in this region are different, they still emphasize people at risk of coronavirus disease, such as healthcare workers, the elderly, and patients with chronic conditions [14]. Thus, the results of the current study showed that most of the participants (31.3%) were healthcare workers (males 64.3%), and most of them (46.3%)



did not affect COVID-19. A similar study was conducted in India, which stated that, according to government regulations, the vaccine was initially administered to healthcare personnel in both government and private hospitals throughout India [15]. Correspondingly, in the US, priority is given mainly to all healthcare workers, then individuals who have an underlying condition, and after that to all essential service workers and older adults [16].

Because of the speed of COVID-19 vaccine manufacturing, concerns among the public have emerged about the safety of these new vaccines. No serious safety problems were reported [17]. Overall, COVID-19 vaccines are safe and will protect the community from developing severe COVID-19 disease and dying from COVID-19. BNT163b2 mRNA COVID-19 vaccine is an mRNA-based vaccine, ChAdOx1 nCoV-19 vaccine is an Adenovirus vaccine, and BBIBP-CorV is a vaccine [18]. According to the research, COVID-19 vaccination adverse effects are characterized as either local or systemic reactions, with severity ranging from mild to moderate [19]. The mRNAbased vaccines such as BNT163b2 mRNA COVID-19 vaccine have the highest level of side effects reported, except for diarrhea and arthralgia [20]. Since some of the vaccinated individuals in the current study received the mRNA-based vaccines, they were not free from side effects. No serious events associated with the COVID-19 vaccines, such as vaccine-induced immune thrombotic thrombocytopenia reported. However, most of the side effects were common and non-lifethreatening. The side effects were systematic and local. The systemic reactions were headache (61.2%), fatigue (49.7%), fever (48.3%), muscle pain (42.9%), joint pain (26.2%), backache (18.4%), chills (16.7%), nausea (10.2%), epigastric pain (7.1%), and rash (1.7%), whereas the local reactions were injection site pain and injection site swelling (50.8%) and (10.5%), respectively. The rarest side effects were tonsillitis (0.7%) and mouth ulcers (0.3%). These findings are in line with those reported in the literature and reported by the Food and Drug Administration (FDA), which are: injection site pain, fatigue, headache, fever, chills, muscle pain, and joint pain are common side effects of COVID-19 vaccines [21, 15]. Similar findings were observed in the Czech Republic



where the most common side effects among vaccinated individuals were injection site pain, fatigue, headache, muscle pain, and feeling unwell [12]. Also, a retrospective cross-sectional study was conducted among Saudi residents to study the side effects of the BNT163b2 mRNA COVID-19 vaccine. The study found that the most common symptoms were injection site pain, fever, headaches, flu-like symptoms, and tiredness. Less common side effects were tachycardia, generalized body aches, shortness of breath, joint pain, chills, and drowsiness. Rare side effects were tenderness, lymph node swelling, and Bell's palsy [22]. In contrast to our study, in a systematic review study, the most common side effects were arthralgia (20). Mild to moderate side effects are experienced by vaccinated individuals. They are signs that the immune system of the body is responding to the vaccine and building protection against the COVID-19 virus (23/24). Also, in the present study, we found that the duration of post-vaccination side effects varied among participants. The majority (41.5%) were complaining about the side effects for two days, whereas 25.2% had side effects for one day, and 10% for three days. Only 3.7% had long-duration side effects for over one month. These findings follow the current studies which state that most of the side effects occur within the next 3 days after vaccination [15]. Also, similar findings were reported by Riad et al., [12]. They found that the duration of general side effects following the vaccine was mainly one day (45.1%) or three days (35.8%), and only 1.4% of them had lasted over a month. Also, it is important to highlight that the prevalence of side effects was higher among younger individuals (> 49 years old) and almost no noticeable side effects occurred among older participants (60 years old). These findings are consistent with those published by the FDA, which found that injection site pain, weariness, headache, and muscle soreness were more common in the 55-year-old group than in the > 55-year-old group [21, 15]. Also, the same findings reported among the Czech Republic and Saudi residents, respectively [12], reported that younger adults 43 years old were more frequently affected by side effects, and [22] concluded that the frequency of side effects was higher in individuals younger than 60 years of age, except for injection site pain, which was more



frequent among those 60 years old.

Concerning the comparison of the occurrence of side effects between BNT163b2 mRNA COVID-19 vaccine, ChAdOx1 nCoV-19 vaccine, and BBIBP-CorV vaccines, the findings of the present study revealed that there were substantial variations between these vaccines in the presence of side effects. The majority (53%) of side effects were because of ChAdOx1 nCoV-19 vaccine, followed by BNT163b2 mRNA COVID-19 vaccine (42%) except for headache, nausea, epigastric pain, fatigue, and tonsillitis which were more sever in BNT163b2 mRNA COVID-19 vaccine than ChAdOx1 nCoV-19 vaccine. The current study found BBIBP-CorV vaccine was safer than BNT163b2 mRNA COVID-19 vaccine and ChAdOx1 nCoV-19 vaccine vaccines in all side effects that occurred among vaccinated individuals. This finding is supported by a systematic review and meta-analysis of randomized control trials (RCTs), which revealed that those who received mRNAbased vaccines had higher rates of side effects in reactogenicity [20]. The same findings were documented in Jordan. 2213 individuals received BBIBP-CorV, ChAdOx1 nCoV-19 vaccine, BNT163b2 mRNA COVID-19 vaccine, and other vaccines. They found that those who received the ChAdOx1 nCoV-19 vaccine reported the most abundant post-vaccination symptoms, while most of those who received the BBIBP-CorV vaccine were free from symptoms [23]. Another study was conducted to assess the symptoms following the COVID-19 vaccine among residents in India. 5396 people responded to the survey. The findings revealed that the frequency of experiencing symptoms following the BBIBP-CorV vaccine was less (24.4%) compared to BNT163b2 mRNA COVID-19 vaccine 70.7% [25]. As seen, the BBIBP-CorV vaccine has few side effects compared to other vaccines.

# **CONCLUSIONS**

The most common side effect of the BNT163b2 mRNA COVID-19 vaccine, ChAdOx1 nCoV-19 vaccine, and BBIBP-CorV among the vaccinated population of the current study was headaches,



injection site pain, injecting site swelling, fatigue, fever, muscle pain, joint pain, backache, chills, nausea, epigastric pain, and rash. These side effects were consistent with the data reported in the literature. Most of these side effects were mild, and no serious incidents were documented. Symptoms were more common in younger people. Although data reported in the literature showed that mRNA-based vaccines such as BNT163b2 mRNA COVID-19 vaccine had higher side effects, However, the current study found that the ChAdOx1 nCoV-19 vaccine, which is an adenovirus-based vaccine, had more side effects than other vaccines, and the BBIBP-CorV vaccine had the lowest side effects compared to the ChAdOx1 nCoV-19 vaccine and BNT163b2 mRNA COVID-19 vaccine vaccines.

#### Limitations

The limitation of the current study is that it was difficult to measure the severity of the side effects because the study is a survey-based technique. Thus some side effects needed to be measured by using instruments or tools, for instance, measuring body temperature by the thermometer to know the severity of fever, and using a pain scale to measure headache, joint pain, and muscle pain. Also it is prone to selective bias as it is internet based study, not everyone has equal chance to be included in the study. Further studies needs to be done with more representative samples concerning COVID-19 intention.

# **Conflict of interest**

The authors have no conflict of interest to declare.

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# The questionnaire

(COVID-19 Vaccines Side Effects Among Iraqi people In Kurdistan Region)

Dears the aim of this survey is to determine the (Prevalence of Covid-19 Vaccines side effects). We are grateful for filling in this survey from you and your family who got vaccinated. I would like to assure you that your answers will remain confidential and your personal details are not required. Also, your answers will be on online systems only.

| 1. Age                                   |
|--|
| 18_25                                    |
| 34_41                                    |
| 50_57                                    |
| 65 and more                              |
| 2. Gender                                |
| Male                                     |
| Female                                   |
| 3. Occupation                            |
| Health care workers  Employee Government |
| Student Own Job                          |
| Jobless                                  |
| 4. Do you have any chronic disease?      |
| Yes                                      |
| No                                       |



| 5. | Did you infected with Covid-19 before?  |
|----|---|
|    | Yes No I don't know   |
| 6. | Which Covid-19 Vaccine you took it?   |
|    | Sinopharm Astrazenea Pfizer   |
| 7. | How many Doses you got it?  |
|    | 1 dose  |
| 8. | Select the vaccine side effects that occurred with you  |
|    | Headache Vaccine injection site pain Fever Nausea Epigastric pain Chills Joint pain Muscles pain Fatigue Injection site swelling Allergy Backache Tonalities Mouth Ulcers |



| Ω | Duration | of side | offoots | of f | Carrid 1 | 10.1 | Vacainas |
|---|----------|---------|---------|------|----------|------|----------|
| 9 | Duration | ot side | effects | OT ( | OVIA-    | 19 ' | vaccines |

| 1 day     |           |  |
|-----------|-----------|--|
| 2 days    |           |  |
| 3 days    |           |  |
| 4 days    |           |  |
| 5 days    |           |  |
| 6 days    |           |  |
| 1 week    |           |  |
| More tha  | n 1 week  |  |
|           | n 1 month |  |
| No durati | on        |  |
|           |           |  |



# The Effect of Spirotive Relaxation Techniques in Reducing the Level of Osteoarthritic Pain in the Elderly: Quasi Experiment Design

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Abstract

**Introduction:** Pain is a common issue in the elderly. Osteoarthritis is often encountered in the

elderly and contributes significantly to pain. Pain complaints involve multifactorial and often face

many hindrances in the management.

**Objective:** This study aims to determine the effect of spirotive relaxation techniques in reducing

osteoarthritis pain scale in the elderly.

Methods: This quasi-experimental study used the Pre-Post Test Control Group Design, conducted

in the Penyengat Olak and Sungai Duren Community Health Center, Jambi Province, Indonesia,

from September to November 2021. Sixty-four elderly participants in this study were divided into

Spirotive relaxation exercise and dhikr as the intervention group and the control group given

Spirotive relaxation exercise only. Data analysis used t-test and independent t-test at a significant

level of 95%.

Results: There are differences in pain levels of the intervention group before and after Spirotive

relaxation exercise and dhikr. Before the intervention, pain levels were moderate to severe, and pain

levels were mild to moderate after the intervention. Similar results were also obtained in the control

group given Spirotive relaxation exercise only with a significant reduction in pain. The independent

test results showed a p-value = 0.207, indicating no difference in osteoarthritis pain in the

intervention and control groups.

**Conclusion:** Spiritual relaxation exercises have been shown to reduce pain levels in the elderly with

osteoarthritis. There are also differences in the level of joint pain scale in the intervention and

control groups. It suggests that public health centers provide non-pharmacological inspirational

interventions as an additional therapy for the elderly.

**Keyword:** Osteoarthritic, Pain, Spirotive, Elderly

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# Introduction

Various health problems will arise along the ageing process and rising age. It is mainly a physical inconveniences problem, such as ailments of musculoskeletal function [1]. Pain in the joints frequently becomes an obstacle for the elderly to carry out daily activities [2,3]. Osteoarthritis is the most common joint disease, which increases in age. The ageing process exerts a shrinking effect on human muscle fibres. Muscle strength will undoubtedly decrease due to the shrinkage of muscle mass impacting the weakness in activity or movement, thereby reducing the quality of life. In addition, it also affects bone mass diminishes. The elderly with regular exercise do not encounter the same loss as the sedentary elderly [4].

Approximately 20% of the world's population obtains joint pain at 55 years old. The current increase in the elderly population goes hand in hand with an increase in the number of cases of joint pain [5,6]. Accordingly, the prevalence of joint disease in Indonesia is 7.3%, of which 45.58% arises in the 56-65 age group, 82.54% is discovered in the female group, and 53.26% complains of knee pain [7].

Knee Osteoarthritis (OA) is a common progressive multifactorial joint disease characterized by chronic pain and functional disability [4]. Knee OA accounts for almost four-fifths of the burden of OA worldwide and increases with obesity and age [6]. Knee arthroplasty is considered an effective treatment at an advanced stage of the disease. However, which is responsible for substantial health costs [5]. Many researchers have shifted their focus to the prevention and treatment in the early stage of the disease [2]. Accordingly, it is essential to understand the prevalence, incidence, and modifiable risk factors of knee OA to provide efficacious preventive strategies [3,8].

Non-pharmacological management of osteoarthritis pain in the elderly include Spirotive Relaxation Exercise (SRE) and dhikr [9]. Spirotive relaxation is a combination and modification of progressive muscle relaxation and spiritual relaxation (dhikr) interventions. Relaxation begins with dhikr, then relaxes muscle tension. Those activities are expected to obtain His grace in the form of peace,



tranquillity, happiness, health and physical fitness. [10].

Spiritual Relaxation (Dhikr) involves praising, remembering, and submitting supplications to God in resignation [11]. Medically, it has been proven that dhikr will automatically stimulate the secretion of endorphins to feel happiness and comfort [12]. Yusuf et al. [11] found changes in psychological well-being in the treatment group before and after the dhikr intervention.

The Spirotive Relaxation Exercise (SRE) is based on the Comfort theory of Kolcaba [13]. Comfort is the main goal in nursing because it is closely related to healing [14–16]. According to Yusuf, et al [11] Spiritual Relaxation intervention can provide comfort by doing SRE and spiritual relaxation (dhikr). Sound waves during dhikr will stimulate auditory receptors. Furthermore, the stimulus will be forwarded to the temporal lobe to catch the point of God (circuit of God). The prefrontal cortex will respond to stimuli at the point of God for the process of forming positive perceptions, both emotionally and spiritually. The amygdala will respond to the prefrontal cortex to the hippocampus as feedback. In addition, the amygdala also stimulates the hypothalamus through the hypothalamic-pituitary-adrenal (HPA) axis to secrete corticotrophin-releasing factor (CRF).

SRE induces muscle contraction of the skeletal fibers, leading to muscle tension [17,18]. In this case, the central nervous system (CNS) involves the sympathetic nervous system and the parasympathetic nervous system [19]. Several organs are affected by these two nervous systems [20]. Sympathetic and parasympathetic nerves work reciprocally. Activation of the parasympathetic nervous system, also called Trophotropic, provides a desire to rest and physical improvement of the body [20,21]. The feeling of comfort and relaxation may reduce even eliminate pain [18,22–24].

Gonçalves, et al [25] stated that dhikr could reduce joint pain in the elderly with knee osteoarthritis. Another study stated that being more active may reduce pain and the risk of functional impairment or disability [26].

Joint pain is a subjective experience that impacts the quality of life and impaired functional activities of the elderly. Therefore, adequate treatment is needed. Non-pharmacological intervention



SRE has the potential to reduce the intensity of osteoarthritis pain. To the best of our knowledge, this has never been studied. Therefore, this study aims to determine the effectiveness of Spirotive Relaxation Exercises to reduce osteoarthritis pain in the elderly.

#### Methods

# Research design

The research design used in this study was Experimental with a Quasi Experiment Design in Pre-Post Test Control Group approach. This study revealed a causal relationship by involving the control group and the experimental group.

# **Research Time and Place**

The study was conducted in the working area of the *Penyengat Olak* and *Sungai Duren* Community Health Center, Jambi Province, Indonesia, from September to November 2021.

# **Participants**

The participants in this study were all the elderly in the Penyengat Olak Health Center (n=32 people) and the elderly at the Sungai Duren Health Center (n=32 people).

# Intervention

SRE is administered independently for 45 minutes twice a week for four weeks. SRE measurement used SOP, While the pain level was measured using the WOMAC Questionnaire. In this index, 24 parameters consisting of pain, stiffness, physical and social function were evaluated using WOMAC. The higher value obtained indicates the magnitude of the patient's functional limitations. The higher the value obtained indicates the magnitude of the patient's functional limitations.

In comparison, the lower value indicates improved functional ability. WOMAC parameters include



(1) the presence of pain, which aspects are assessed when walking, climbing stairs, doing activities at night, at rest and when supporting (2) the presence of stiffness in the morning and stiffness throughout the day (3) the state of physical function Patients have difficulty going downstairs, difficulty going upstairs, difficulty from sitting to standing, difficulty standing, difficulty sitting on the floor, difficulty walking on a flat surface, difficulty getting in and out of a vehicle, difficulty shopping, difficulty wearing socks, difficulty lying in bed, difficulty taking off socks, difficulty sitting, difficulty doing heavy tasks and difficulty doing light tasks. WOMAC produces an algorithmic value obtained from a questionnaire to measure pain and disability in patients' knees. In the questionnaire, the answers were given a 0 - 4. Each score represents the patient's perceived state. Details of the WOMAC questionnaire can be seen in the table. Furthermore, the scores of the 24 questions are added up divided by 96 and multiplied by 100% to find out the total score and categorized as Mild (0-40%), moderate (40%-70%), and severe (70%-100%). The greater the score, the more severe the pain and disability of the knee [27,28].

The Assessment of pain is based on stiffness and physical function with mild, moderate, and severe categories. The intervention group was given SRE and reciting dhikr, while the control group only received SRE.

#### **Outcomes**

The output of this study was to determine the level of pain and the differences in pain levels before and after giving spirotive relaxation exercises.

# Sample size

The sample in the current study was 64 participants divided into two groups, 32 participants as group intervention and 32 participants as group control. The minimum sample size was determined using the GPower software version 3.1.9.4, where the effect size d = 0.63, alpha = 0.05, at power



0.80 with a sample ratio of 1:1. The sample size for group 1 was 32 and group 2 was 32 for a total of 64. The sample was randomly selected. The sample size in the study initially involved 124 potential participants, whereas 60 people did not meet the criteria. The inclusion criteria for the sample were 45-80 years old, a minimum education level of Elementary School (SD), and no cognitive impairment (MMSE score >23). At the same time, the elderly with limited range of motion and bed rest were excluded.

# Randomisation

Participants were selected from the total population using a simple random technique. Sample selection includes determining prospective participants, selecting participants, and reporting participants to researchers. Enumerators received a briefing on applying the sample selection mechanism for the provision of SRE and dhikr.

# Blinding

The included samples were selected blindly. The enumerator who had been assigned by the researcher did not previously know the potential participants.

#### **Ethical Consideration**

No economic incentives were offered or provided for participation in this study. The study was performed under the ethical considerations of the Helsinki Declaration by the Health Research Ethics Commission of the Ministry of Health, Jambi, and registration number: LB.02.06/2/59/2021.

# Statistical analysis

Description of participant characteristics (age, gender, education level, and occupation) and osteoarthritis pain before and after the intervention is based on univariate analysis results. Data are



presented as numbers and percentages for categorical variables. Continuous data were expressed as  $mean \pm standard$  deviation (SD) or median with Interquartile Range (IQR). The normality test used the Kolmogorov-Smirnov test with Lilliefors significance correction.

In bivariate analysis, a t-test was used to assess the effect of spiritual healing and dhikr in the intervention and control groups. In contrast, an independent t-test was used to determine differences in osteoarthritis pain intensity between the two study groups. All tests with p-value (p)<0.05 were considered significant. Statistical analysis was performed using SPSS version 16.0.

**Results**The characteristics of respondents are presented in table 1 below:

| Cl. 1 CD. 1                    | Group  |         |    |       |
|--------------------------------|--------|---------|----|-------|
| Characteristics of Respondents | Interv | vention | Co | ntrol |
|                                | N      | %       | N  | %     |
| Sex                            |        |         |    |       |
| Man                            | 12     | 37.5    | 10 | 31.3  |
| Female                         | 20     | 62.5    | 22 | 68.7  |
| Age                            |        |         |    |       |
| 45-59 y.o                      | 12     | 37.5    | 14 | 43.8  |
| 60-74 y.o                      | 18     | 56.3    | 17 | 53.1  |
| 75-90 y.o                      | 2      | 6.2     | 1  | 3.1   |
| <b>Education Level</b>         |        |         |    |       |
| Primary school                 | 6      | 18.8    | 9  | 28.1  |
| Junior high school             | 17     | 53.0    | 16 | 50.0  |
| Senior High School             | 6      | 18.8    | 5  | 15.6  |
| College                        | 3      | 9.4     | 2  | 6.3   |
| Occupation                     |        |         |    |       |
| Work                           | 4      | 12.5    | 3  | 9.3   |
| No work                        | 28     | 87.5    | 29 | 90.7  |

**Table 1.** Characteristics of Respondents

Characteristics of respondents from the two groups are based on gender, primarily female, 62.5% from the intervention group, and 68.7% from the control group. The characteristics of respondents based on age were mainly in the elderly group (60-74) years, 56.3% in the intervention group, and 53.1% in the control group. Based on education level, most respondents were junior high school, as



much as 53% in the intervention group and 50% in the control group. Characteristics of respondents based on the type of work show that most respondents did not work, as much as 87.5% in the intervention group and 90.7% in the control group.

The description of osteoarthritis pain in the intervention group before and after the intervention presented in table 2 below:

| Pain scale | Pre | test | Post test |      |  |
|------------|-----|------|-----------|------|--|
|            | n   | %    | n         | %    |  |
| Mild       | 2   | 6.3  | 12        | 37.5 |  |
| Moderate   | 15  | 46.9 | 18        | 56.2 |  |
| Severe     | 15  | 46.9 | 2         | 6.3  |  |

**Table 2.** Description of pain scale before and after spirotive intervention in the intervention group

Table 2 shows that the scale of osteoarthritis pain before the SRE was mild pain (6.3%), moderate pain (46.9%), and severe pain (46.9%). The osteoarthritis pain scale felt by respondents after the SRE was mild pain (37.5%), moderate pain (56.3%), and severe pain (6.3%).

The description of osteoarthritis pain in the control group before and after the intervention presented in table 3 below:

| Pain scale | Pre test |      | Post test |      |  |
|------------|----------|------|-----------|------|--|
|            | n        | %    | n         | %    |  |
| Mild       | 5        | 15.6 | 19        | 59.4 |  |
| Moderate   | 21       | 65.6 | 12        | 37.5 |  |
| Severe     | 6        | 18.8 | 1         | 3.1  |  |

**Table 3.** Description of pain scale before and after spirotive intervention in the control group

Table 3 shows that the scale of osteoarthritis pain before SRE was 15.6% in mild pain, 65.6% in moderate pain, and 18.8% in severe pain. After the intervention, it was found that participants felt



mild pain (59.4%), moderate pain (37.5%), and severe pain (3.1%).

Furthermore, the data normality test was carried out using the Kolmogorov-Smirnov test to determine the distribution of research data. The results of the data normality test are presented in table 4 below:

| Group        | N  | mean±SD     | Kolmogorov-Smirnov test |
|--------------|----|-------------|-------------------------|
| Intervention | 32 | 58.26±14.86 | 0.801                   |
| Control      | 32 | 47.58±7.26  | 0.424                   |

Table 4. Data Normality Test

Table 4 shows that the p-value of the intervention group > 0.05, as well as the p-value of the control group > 0.05, so it can be concluded that the data is normally distributed.

The condition of painful scale before and after the intervention in Group 1 and Group 2 can be seen in the table 5 below:

|                                    |    | t test          |                  | independent t test     |
|------------------------------------|----|-----------------|------------------|------------------------|
| <b>Interventions Group 1 and 2</b> | N  | Group           | Group            |                        |
|                                    |    | intervention    | control          | Group intervention vs. |
|                                    |    | Mean±SD         | Mean±SD          | Group control          |
|                                    |    | Median (IRQ)    | Median (IRQ)     |                        |
| Pre-test                           | 32 | 68.31±18.28     | 54.56±19.64      |                        |
|                                    |    | 68.5 (55-82)    | 56 (44.75-69.25) | p-value = $0.005$      |
| Post-test                          | 32 | $48.21\pm26.35$ | 40.59±21.16      |                        |
|                                    |    | 46 (23-74.5)    | 34 (23-56)       | p-value = 0.207        |
| p-value                            |    | 0.0001          | 0.001            |                        |

**Table 5.** Frequency distribution of Group Intervention and Group Control before and after interventions

Table 5 shows a significant decrease in pain level in both groups before and after the intervention with a p-value <0.05. Based on the t independent test, it was found that the p-value for the pre-test (<0.005) and the post-test was 0.207. The post-test value showed no difference between the two



research groups.

#### **Discussions**

The t-test result of pre-post intervention revealed a decrease in pain. In both the intervention and control groups, the p-value was <0.05. The independent t-test showed differences in the two groups before the intervention with a p-value <0.05, but after the intervention (post-test), the p-value was >0.05. It indicates that SRE and dhikr therapy may reduce knee OA pain in the elderly.

Older people with osteoarthritis often run into joint pain [29,30]. These complaints are often found in geriatric care in the community and clinic. This study provides an SRE intervention with a combination of spiritual techniques: dhikr (spirotive) to reduce joint pain in the elderly with osteoarthritis [24]. Joint disease is a degenerative process and causes pain in the elderly [31]. Pain itself can be caused by several conditions, including rheumatoid arthritis, gout (uric acid), and osteoarthritis [32]. SRE is a technique for reducing muscle tension by a simple and systematic process of stretching a group of muscles and then relaxing back [33].

SRE focuses on maintaining a deep form of relaxation, applying contraction and relaxation of various muscle groups from the feet up or from the head down. This method will realise where the muscles are located and increase awareness of the body's muscle response [34,35]. SRE may reduce pain, anxiety, depression, improve sleep quality, and reduce fatigue [36].

Religious relaxation (dhikr) is a technique that includes a belief factor. In this study, we used the element of Islamic belief with the repeated praise of God's name submissively [11]. Religious relaxation: dhikr is one of the efforts to meet the psychological needs of the elderly through the fulfillment of spiritual needs. It is also a practice of prayer to God by continuously remembering God name submissively. The essence of dhikr is praying for forgiveness, praising and glorifying God, being grateful, takbir to humble before God. Finally, eliminate ourselves and our ego against God's ego in all the activities we do [37].



Dhikr relaxes the body and produces impulses sent through afferent nerve fibers. Physiologically, spiritual therapy by dhikr or remembering God's name causes the brain to work. When the brain gets external stimulation, it will produce neuropeptides chemicals to provide comfort. The substances will be involved and absorbed in the body, providing feedback in comfort. Psychologically dhikr will balance serotonin and norepinephrine levels in the body. This phenomenon is natural morphine that works in the brain and will cause the heart and mind to feel calm compared to before dhikr [37].

The results of this study must be interpreted cautious because the limitations of this study are: the patient was not directly supervised by the researcher in doing dhikr. It is difficult to determine the quality of dhikr performed by a person, and there are no clear parameters to determine it. Supposedly, the acceptable quality of dhikr will give a calming effect. It could result in no difference in pain levels between the two groups after the intervention. In future studies, supervision should be conducted strictly when the intervention ensues. The strength of this study lies in its RCT design, using an intervention that has never been done before in patients with osteoarthritis pain.

#### Conclusion

SRE has been proven to reduce joint pain scale in the elderly with osteoarthritis, and there are also differences in joint pain scale levels in the intervention and control groups.

It is suggested that the community health centers may use SRE as an additional therapy for the elderly. Increasing the capacity of elderly health assistance needs to be carried out by the community health centers to increase the knowledge and behavior of the elderly in overcoming problems related to their degenerative conditions.

#### The limitations

The limitations of this study include a small sample and only involving respondents in one country, namely Indonesia, so it cannot compare the intervention responses in each different ethnic group.



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# **Competing interests statement**

There are no competing interests for this study.



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# Assessing the outcome of admissions: Pilot study in a High Intensity Psychiatric Residential Facility

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## **ABSTRACT**

Background: The Italian health system related to mental disorders is currently experiencing a period of radical reforms. This process began in 1978 with the adoption of the law 180 which produced a radical reform in mental health care. The problems of the continuous confrontation with increasing levels of expenditure are reflected in the search for models to improve both the efficiency and effectiveness of the health care system. Among these, the value creation model proposes to optimize the relationship between effectiveness, quality, and appropriateness of care on the one hand, and efficiency, cost and how resources are used on the other. The intervention involves redesigning services on the principles of recovery; implementing treatments supported by scientific evidence; encouraging processes of social inclusion. The proposed rehabilitation interventions are recovery oriented that place the person at the center of his rehabilitation path, motivating him in assuming responsibility for the treatment proposed during hospitalization.

**Objective:** Evaluate the impact of the organisational reorganisation of the DSM S.R.R Regional Health Service of Ancona Area Vasta 2 by introducing evidence-based and recovery-oriented practices through the evaluation of clinical outcomes and psychosocial functioning.

**Methods:** Longitudinal descriptive observational study with evaluation of a cohort of 13 patients, hospitalized in residential and semi-residential care at SRP1 "Casa Rossa" Area Vasta 2 of Ancona, by administration of a questionnaire (HoNOS) at the time of recruitment (February 2019), at 6 months (August 2019) and at 12 months (February 2020). The 12 items of the questionnaire were grouped into four subsets: behavioural problems (items 1-3), deficits and disabilities (items 4-5), psychopathological symptoms (items 6-8) and relational/environmental problems (items 9-12).

**Results:** Survey results show a reduction in mean scores at 6 and 12 months compared to baseline in all subscales.

**Conclusions:** Intensive mental health residential facilities need to put more effort into evaluating effectiveness in practice, using appropriate tools for outcome assessment and analysis of results. It



is possible, in daily clinical practice, to evaluate the outcome of admissions in order to satisfactorily describe the changes induced during the period of hospitalization.

Keywords: outcome of care, mental health, psychiatric facility, biopsychosocial.



## INTRODUCTION

The Department of Mental Health (DSM in Italian) is the set of facilities and services whose task is to take charge of the demand for care, assistance and protection of mental health; it is the body which governs, coordinates and manages Community Psychiatry, guaranteeing the unity and integration of psychiatric services within the area of competence defined by ASUR Marche [1]. Moreover, the DSM's task is to promote mental health and quality of life in the target population; to guarantee primary and secondary prevention of mental disorders with the early detection of situations of distress and tertiary prevention with the reconstruction of the affective, relational, social and work fabric [2]. The typology of psychiatric residential facilities is distinguished both by the level of therapeutic-rehabilitative intervention, related to the level of impairment of the patient's functions and abilities (and its treatability), and by the level of care intensity offered, related to the overall degree of autonomy. Psychiatric residential facilities for intensive therapeutic rehabilitation treatment (SRP1) are facilities for patients with severely impaired personal and social functioning. These structures play a transitional role, aimed at reintegrating the patient into his/her usual living environment (generally family) [3,4]. The intervention areas of SPR1 concern the clinical psychiatric, psychological, rehabilitation, resocialisation and coordination areas. The new organisation of the Psychiatric Residential Facilities (SRP in Italian) of the Area Vasta 2 DSM is part of the new organisation suggested by the Unified Conference Agreement of 17 October 2013 [5] and subsequently accepted at regional level by D.G.R.M. 1331/14 [6], where the concept of residency is declined in a different way of managing psychological distress. The user is no longer placed in a purely medical dimension, but an individual project is built in agreement with other professionals. Therefore, the care pathway must be configured as a project characterised by: unity, continuity, multidisciplinarity, high organisational complexity, relevant professional specificity and ability to manage sociomedical integration [7]. It is based on the integration of specific activities such as: clinical and rehabilitation activities, care activities,



family and social mediation, networking and coordination. The realisation of this pathway implies a strong investment in team work, understood as a multi-professional group able to develop an accurate reading of the patient's biopsychosocial dimension, to integrate the observation data and to modulate a coherently articulated therapeutic planning. Thus, the 'biopsychosocial' model systematically employs biological, psychological and social factors, including their complex interactions, in the understanding of psychophysical health and the choice of therapeutic intervention [8]. Consequently, by focusing on the unitary and global approach to the person, the biopsychosocial model is the one most conducive to an interdisciplinary approach between the various professions, such as doctors, psychologists, social workers and educators. For patients with severe mental illnesses, controlling symptoms, regaining a positive sense of self, dealing with stigma and discrimination, and trying to lead a productive and satisfying life is increasingly referred to as an ongoing process of recovery [9]. Equally important is to enhance personal attitudes and skills such as communication skills, enthusiasm and willingness to learn, cultural background and to develop the practice of outcome assessment among practitioners. Patient care in residential psychiatric facilities is therefore linked to a practice oriented towards therapeutic continuity and is implemented through individual projects [10].

In past years, at national and regional level, activity data have shown a progressive lengthening of hospital stays, with a consequent reduction in patient turnover. In this sense, psychiatric residency has often taken on the function of a 'housing solution' rather than being functional to the 'individual treatment project', generating the danger that SRPs are used for forms of new institutionalisation. All SRPs should therefore provide for light residential care with assistance, which facilitates the transition from the structure to the territory [3]. There is a need for evidence-based assessment and rehabilitation activities in order to provide residents with the possibility of being involved in social interactions outside of the facilities, and possibly with opportunities for sheltered work and social integration. Indeed, work, social relationships and independence are



aspects of quality of life recognised as important by both patients and their treating physicians [11]. Well-designed rehabilitation plans, adapted to the needs of each patient, are mandatory to foster the development of independence, increase the likelihood of discharge and ultimately improve quality of life [12]. The development of the clinical pathways model requires addressing fundamental clinical and organisational aspects [13]:

- organising a reception/assessment function for demand and requests from psychiatric services;
- the centrality of the sending Mental Health Centre (CSM in Italian);
- the centrality of family;
- the involvement of the GP to be implemented from the earliest stages of the patient's contact with the structure;
- the definition and organisation of individualised therapeutic-rehabilitation paths;
- facilitating access procedures for all DSM operators;
- defining criteria for a maximum length of stay consistent with the level of rehabilitation intensity (18/24 months for rehabilitation facilities, 36 months for care facilities).

The result of the change process was to orientate the whole Structure to adopt principles, develop policies and implement actions, in order to help people with mental disabilities to remain in their life context, trying to achieve the best possible biopsychosocial functioning compatible with functional deficits, persistent psychopathology and relapses.

## MATERIALS AND METHODS

## Study design



Longitudinal descriptive observational study by administering the HoNOS questionnaire after the reorganisation of the psychiatric residential facilities of the Department of Mental Health of the Ancona Vasta 2 Area.

# **Population and settings**

The pilot study was conducted at SRP1 "Casa Rossa" Area Vasta 2 of Ancona and involved 13 patients admitted to SRP1 Casa Rossa - AN ASUR Marche.

#### **Inclusion criteria**

Residential and semi-residential patients.

## **Ethical consideration**

After explaining the purpose, the study was authorised by the Director of the DSM.

The study protocol was developed in accordance with the guidelines of the Declaration of Helsinki. Participation in the study was voluntary: patients were provided with a consent form for data processing and an information and consent form for the study. Only after obtaining consent and ensuring that the patient understood the purpose of the study was the paper-based HONOS questionnaire administered. Data were collected after obtaining informed consent from each patient. The confidentiality of the data collected was guaranteed by ensuring the anonymity of all participants and avoiding the use of any personal identifiers. The surveys, carried out in a homogeneous way by the Coordinator of the Operating Unit with over thirty years of working experience (twenty years of experience in the mental health area) took place in a protected environment, with a standardised method: a room specifically dedicated to surveys and data collection, no outside involvement and respect for the patient's privacy.



# **Survey instrument**

The validated Italian version of the Health of the Nation Outcome Scales [14] was used.

The HoNOS scale is a multidimensional outcome and severity assessment tool developed specifically for routine use in mental health services, suitable for the assessment of clinical and psychosocial problems [15,16]. It consists of 12 items that the therapist assesses according to the severity of the problems. Each item represents a clinical problem area and is rated on a 5-point Likert scale. Relevant items include:

- 1. Hyperactive, aggressive, destructive or agitated behaviour;
- 2. Deliberately self-harming behaviour;
- 3. Problems related to drug or alcohol use;
- 4. Cognitive problems;
- 5. Problems of somatic illness or physical disability;
- 6. Problems of somatic illness or physical disability;
- 7. Problems related to depressed mood;
- 8. Other mental and behavioural problems;
- 9. Relational problems;
- 10. Problems in activities of daily living;
- 11. Problems in living conditions;
- 12. Problems in the availability of resources for work or leisure activities.

Each of the twelve items in the questionnaire is given a score from 0 to 4, where:

- a score of 0 indicates that no problem has been found;
- a score of 1 indicates that the problem is present, but because of its reduced severity no
  intervention is needed;



- a *score of 2* indicates that a problem of mild severity is present, for which intervention (rehabilitation, care or therapy) is required;
- score 3 indicates the presence of a problem of moderate severity;
- a score of 4 indicates that a serious or very serious problem is present.

Unknown information was given a score of 9. The twelve scores can be added together to obtain an estimate of total severity or evaluated individually.

## Study procedures and data collection

The reconversion project of SRP1 "Casa Rossa" took place in accordance with the principle of gradualness and with the participation of all operators through weekly meetings specifically planned by the nursing coordinator. Subsequently, patients were assessed three times over a one-year period by administration of the HoNOS questionnaire, at recruitment (February 2019), at 6 months (August 2019) and at 12 months (February 2020). Patients excluded from care were not included in the study. After data collection, the 12 items of the HoNOS scale were grouped into four subscales:

- 1. behavioural problems (items 1-3),
- 2. deficits and disabilities (items 4-5),
- 3. psychopathological symptoms (items 6-8)
- 4. relational/environmental problems (items 9-12).

# Statistical analyses

Data was expressed as mean and standard deviation (SD) or median and interquartile range (IQR) in the case of numerical variables, while in the case of qualitative variables, it was expressed as



absolute numbers or percentages. The normality of the data was checked with the Shapiro-Wilk test, where with a p-value > 0.05 there is evidence of normally distributed data.

The difference between the averages of the total score and the scores of the four subscales, at the three follow-up points, was statistically evaluated with an analysis of variance model for repeated measures, in the case of normally distributed residuals; in the case of non-normally distributed data, the non-parametric Friedman test was applied.

For the scales with statistically significant differences in scores, multiple comparisons were made retrospectively between the groups (baseline, 6 months, 12 months) maintaining the 5% significance level with Bonferroni correction.

Statistical analyses were carried out using the software R-CRAN v.3.6.2 for Windows.

# **RESULTS**

Table 1 shows the demographic and clinical characteristics of the cohort of patients examined in the study.

| Demographic/clinical variable    | N(%)      |  |  |
|----------------------------------|-----------|--|--|
| Age at enrolment (mean, SD)      | 45.6(8.2) |  |  |
| Age at onset (mean, SD)          | 19.2(3.2) |  |  |
| Gender:Male                      | 9(69.2%)  |  |  |
| Caregiver:Yes                    | 6(46.2%)  |  |  |
| Other rehabilitation courses:Yes | 5(38.5%)  |  |  |

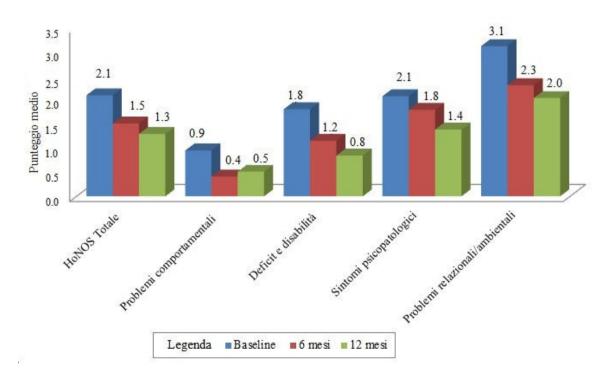
**Table 1.** *Descriptive statistics for demographic and clinical variables.* 

The mean with the standard deviation and the median with the interquartile range of the total score and the scores of the items of the 4 sub-scales, at baseline and in the two surveys at follow-up, are shown in table 2 and figure 1.



| Scale of<br>Evaluation            | Ba        | seline        | 6 months  |               | 12 months |               |
|-----------------------------------|-----------|---------------|-----------|---------------|-----------|---------------|
|                                   | Mean (SD) | Median (IQR)  | Mean (SD) | Median (IQR)  | Mean (SD) | Median (IQR)  |
| HoNOS Total                       | 2.1 (0.4) | 2.1 (1.8-2.3) | 1.5 (0.3) | 1.5 (1.3-1.6) | 1.3 (0.3) | 1.3 (1.2-1.4) |
| Behavioural problems              | 0.9 (0.6) | 1.0 (0.7-1.3) | 0.4 (0.4) | 0.3 (0.0-0.7) | 0.5 (0.5) | 0.3 (0.0-0.7) |
| Deficits and Disabilities         | 1.8 (1)   | 1.5 (1.0-2.5) | 1.2 (0.9) | 1.0 (0.5-2.0) | 0.8 (0.6) | 0.5 (0.5-1.5) |
| Psychopathological symptoms       | 2.1 (0.9) | 2.3 (1.3-2.7) | 1.8 (0.6) | 1.7 (1.3-2.0) | 1.4 (0.5) | 1.3 (1.0-1.7) |
| Relational/environmental problems | 3.1 (0.6) | 3.0 (3.0-3.8) | 2.3 (0.4) | 2.3 (2.0-2.5) | 2.0 (0.4) | 2.0 (2.0-2.0) |

**Table 2.** Mean, standard deviation, median and interquartile range of Total Scale and 4 Subscales scores at baseline, 6 months and 12 months.



**Figure 1.** Average total score and average score of the 4 sub-scales.



The residuals of the analysis of variance model are distributed in accordance with the Normal random variable for the subscales of "deficit and disability" and "psychopathological symptoms" (p-value>0.05); the scale HoNOS Total, that of behavioural problems and of relational/environmental problems do not present normally distributed residuals (table 3).

| Scale of evaluation               | p-value |
|-----------------------------------|---------|
| HoNOS Total                       | 0.0319  |
| Behavioural problems              | 0.0394  |
| Deficits and Disabilities         | 0.0596  |
| Psychopathological symptoms       | 0.3999  |
| Relational/environmental problems | 0.0388  |

Table 3. P-value Shapiro-Wilk normality test

The statistical significance (p-value) of the differences between the averages of the total score and the scores of the four subscales at the three follow-up points are given in Table 4; the results show a statistically significant difference between the averages at the 95% confidence level.

| Scale of evaluation               | Statistical test | P-value  |  |  |
|-----------------------------------|------------------|----------|--|--|
| HoNOS Total                       | Friedman         | <0.0001  |  |  |
| Behavioural problems              | Friedman         | 0.0024   |  |  |
| Deficits and Disabilities         | ANOVA            | < 0.0001 |  |  |
| Psychopathological symptoms       | ANOVA            | < 0.0001 |  |  |
| Relational/environmental problems | Friedman         | 0.0024   |  |  |

**Table 4.** Statistical significance of ANOVA and Friedman's Test.

Table 5 shows the p-values of multiple retrospective comparisons between the groups (baseline, 6 months, 12 months) while maintaining the 5% significance level with the Bonferroni correction.



|                                   | P-value Post - Hoc Test (Bonferroni Correction) |                       |                          |  |  |
|-----------------------------------|---|-----------------------|--------------------------|--|--|
| Scale of evaluation               | 6 months VS<br>Baseline                         | 12 months VS Baseline | 12 months VS 6<br>months |  |  |
| HoNOS Total                       | 0.0070*   | 0.0050*               | 0.0320*                  |  |  |
| Behavioural problems              | 0.0190*   | 0.0250*               | 1.0000                   |  |  |
| Deficits and Disabilities         | 0.0080*   | <0.0001*              | 0.1180                   |  |  |
| Psychopathological symptoms       | 0.6900  | 0.0030*               | 0.0330*                  |  |  |
| Relational/environmental problems | 0.0150*   | 0.0070*               | 0.4740                   |  |  |

<sup>\*</sup>P-value < 0.05 Statistically significant difference

**Table 5.** *P-value of pairwise retrospective comparisons of scores on the HoNOS Total scale and the 4 subscales at baseline, 6 months and 12 months.* 

## **DISCUSSION**

The study performed predates the SARS-CoV2 pandemic and involved a cohort of 13 patients admitted to SRP1 Casa Rossa in Ancona. The mean age at recruitment and at disease onset was 46 and 19 years respectively, 69% of patients were male, 46% had a caregiver and 38.5% had undertaken other rehabilitation pathways. The results of the study show a reduction in the average HoNOS scale scores at 6 and 12 months compared to baseline in the four subscales considered. Considering the HoNOS scale in its entirety, there was a considerable decrease in the score from an overall mean of 2.1 at baseline to 1.3 at the end of the 12-month study period (Table 2). In all subscales considered, this decrease is statistically significant. The analysis of the data showed that the adjustment of the organisational set-up produces greater improvements especially in the initial phase (after 6 months) with a very significant decrease in average scores. After 6 months from the start of the study there is a stabilisation of the average HoNOS Total and subscale scores. Table 5



shows the p-values of the multiple comparisons between the groups; the scores of the groups compared were statistically significant with the exception of the scores taken at 6 and 12 months for the subscales of "behavioural problems", "deficits and disabilities" and "relational/environmental problems" and the scores taken at 6 months and at baseline for "psychopathological symptoms".

Similarly to a study by Buratti et al. [17], it is important to underline that, in the face of a clear prevalence of pharmacological treatments, the items that undergo a clear improvement are precisely those on which the drug has a direct effect (e.g. items concerning behavioural problems, deficits and disabilities and psychopathological symptoms), while the items concerning problems that would also require the use of other types of treatments (e.g. relational, environmental items) show a smaller decrease in average scores. Other data in the literature demonstrate the importance of using the HoNOS scale for assessing outcomes in patients with mental illness. A first longitudinal study in 3 times (14 months) was carried out in the Mental Health Services of the A.O. Ospedale Niguarda Ca' Granda in order to contribute to the validation of the Italian version of the HoNOS scale and to make operators aware of the importance of a standardised assessment of outcomes. With regard to the results on improvement (clinically significant criterion of 7 points), improved patients correspond to 45.3% of the sample after 14 months from the start of the study [16]. Two other longitudinal studies [18,19] in three stages and with a two-year follow-up, were implemented in a Mental Health Centre in Rome where the following were analysed: the relationship between the severity detected by HoNOS and the ICD-9-CM diagnosis; the convergence between the two instruments; the relationship between HoNOS severity and the types of interventions used by the Mental Health Centre (psychiatric interview, psychological interview, psychotherapy, pharmacotherapy, home visits, rehabilitation, insertion in residential facilities) in order to assess the distribution of resources and finally the improvement of patients in one year. The results found convergence between HoNOS and ICD-9, appropriate use of interventions in



relation to the specificity and severity of the diagnosis, and an improvement in patients with a significant decrease in mean scores.

Further studies have involved the Mental Health Departments of the A.O. Ospedale Niguarda Ca' Granda as part of the introduction of a tool to formalize the Individual Treatment Plan (I.T.P.) in which the HoNOS scale is used for assessment and final evaluation of the chosen treatment [19,20]. In this research several aspects were evaluated: the type of intervention foreseen (counselling, intake, treatment), the treatments carried out (pharmacotherapy, psychotherapy, work placement, family involvement, etc.), the outcome of the intervention (re-evaluation at 6 months in case of intake and treatment), drop-out, costs, the role of the case manager and the impact on the work of the operators. The results showed a statistically and clinically significant improvement in severity scores even though there was a medical/nursing imbalance in the treatments provided. The number of psychological, social and rehabilitation treatments is still too low. In psychiatric services, the professional figure and services of psychiatrists predominate, to the detriment of the scarce presence of psychologists/psychotherapists, despite the fact that psychotherapy has been shown to bring about greater and more constant changes over time than the use of medication alone [19]. For this reason, one of the innovative elements in the study was to go beyond the medical-centric model in favour of interdisciplinary teamwork. In community psychiatry, all professionals must be united by a single aim: to provide patients with opportunities to use the skills learned in rehabilitation programmes in natural environments and to increase the quality of their lives. In order to ensure such integration, it is necessary to establish and implement an interdisciplinary and multidisciplinary team, whose operation is ensured by individual and collective tasks, well-defined performance standards, supervision and continuous on-the-job training [21]. It becomes a moral duty to assess whether in one's own reality, with one's own patients, colleagues, organisational difficulties and shortcomings, one can achieve the same results as in experimental effectiveness studies. It is possible, in everyday clinical practice, to routinely



assess the outcome of hospitalisation using a scale such as the HoNOS, because not only is it simple and quick to fill in, but above all because it satisfactorily describes the changes induced by the period of hospitalisation.

#### **CONCLUSIONS**

In recent decades, mental health care has seen a shift from symptom management to the promotion of quality of life within psychiatric facilities: both patients and their relatives consider quality of life as one of the main goals of mental health care [22]. Rehabilitation facilities should be aimed at social integration; provide for a maximum length of stay of 24 months, with a 24-hour presence of health and psycho-socio-educational staff; provide for areas of involvement of patients and relatives [5]. The results of this pilot study show how an organisational reorganisation aimed at adopting principles, developing policies and implementing actions to help people with mental disabilities can improve the quality of hospitalisation and consequently the quality of life of patients with mental disorders. Achieving the best possible biopsychosocial functioning compatible with functional deficits, persistent psychopathology and relapses, involving the family and the general practitioner from the earliest stages of the patient's contact with the facility are fundamental aspects of a care pathway for patients with mental disorders. At the end of a residential treatment programme, there should be a continuation of rehabilitation and care treatment by the mental health centres (CSM) in the region, where there is support and home visits through a single and integrated socio-health pathway with re-evaluation over time of patients under treatment for mental disorders. The evaluative approach should not be seen by practitioners as an inquisitorial control, but as an opportunity geared towards improving care, the severity of patients and the outcome of their treatment. The use of HoNOS in Psychiatric Facilities should not be considered as a goal, but as a starting point for a journey towards a more adequate clinical



practice for the management of patients with mental disorders, which favours the effectiveness of treatments and the self-reflection of professionals [16].

# LIMITATIONS OF THE STUDY

Despite the supervision of the nursing coordinator and the medical director of the facility, a potential information bias due to the detector effect (degree of subjective evaluation of information) is present and cannot be eliminated. The main limitation is the small sample size, which does not allow confounding factors such as diagnosis, age at onset, etc. to be taken into account in the statistical analysis. Although the results show a reduction in mean scores at 6 and 12 months compared to baseline, a longer observation period would be desirable to allow further evaluations of the effectiveness of the biopsychosocial intervention.

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# **CONFLICTS OF INTEREST**

The authors declare that they received no funding for the following study and have no financial interest in the subject matter or the results obtained.



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# Nurses' experiences and emotions in the face of changes caused by the COVID-19 pandemic: a phenomenological study

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## **ABSTRACT**

**Introduction**: Following the Covid-19 pandemic, healthcare personnel had to face a very difficult period linked to the healthcare emergency, with important repercussions from a professional and personal point of view. These aspects have been explored by numerous researches on an international level, but only a small number of articles have investigated the phenomenon in the Italian context. The aim of this research is to describe the experience of healthcare workers in a Covid ward, exploring their emotional responses.

**Materials and Methods**: The study consists of a qualitative research with a phenomenological approach according to Giorgi. Narrative interviews were used with healthcare workers who worked in a Covid ward at the San Camillo health centre in Turin, a hospital specialising in second level functional recovery and re-education.

Results: Through the field research, 12 interviews were collected, involving 9 nurses and 3 social-health workers, working in a ward dedicated to the care of Covid-19 patients. The common themes that emerged concerned: the beginning of the Covid operator's "journey", characterised by a profound change in professional life since the beginning of the pandemic; the whirlwind of emotions and feelings experienced (fear, feeling blocked, annulled, powerless, depersonalised by suits and masks, anguish due to both physical and psychological isolation, etc.); relations with family members and friends; the relationship with the patient's family; relations with the operators' families; the risk of contagion and the fear of infecting oneself and one's loved ones; the group as a handhold for not giving up, as a point of strength, union and trust; the awareness of change with the desire to take one's own life back into one's own hands, taking advantage of the good things this time can give.

**Conclusions**: The research highlights the ability of the operators to identify positive aspects in the experiences lived, the union and trust in the group and the support of the family despite the strong fear of contagion. There are also important suggestions to reinforce strategies for dealing with such



health emergencies and the importance for each individual in feeling accompanied throughout the process, in the difficult challenges they face.

Keywords: Covid-19, Experiences, Nursing, Narrative, Phenomenological approach.



## INTRODUCTION

On 31 December 2019, Chinese Health Authorities reported to the World Health Organisation a cluster of cases of pneumonia of unknown aetiology in the city of Wuhan, in China's Hubei province, On 9 January 2020, the Centre for Disease Control and Prevention of China reported that a new coronavirus (SARS-CoV-2)<sup>[1]</sup> was identified as the causative agent of the respiratory disease later named Covid-19. China made public the genome sequence that enabled a diagnostic test and on 30 January 2020, the World Health Organisation (WHO)<sup>[2]</sup> declared the Coronavirus outbreak in China to be an "International Public Health Emergency" [3,4]. From then on, the word 'COVID-19' has indicated the disease associated with the SARS-CoV-2 virus (severe acute respiratory syndrome coronavirus 2), characterised by mild symptoms (fever, sore throat, fatigue, muscle pain, loss of taste and smell) or more severe symptoms (pneumonia, respiratory failure)<sup>[5]</sup>. Such symptoms have often led to the need for intensive care<sup>[6,7]</sup>, thus causing high pressure on hospitals struggling to cope with too many patients to care for [8]. In this catastrophic scenario linked to the epidemic, Italy was one of the countries most affected<sup>[9]</sup>. Between the beginning of February and 30 November 2020, 1,651,229 positive Covid-19 cases were diagnosed by Regional Reference Laboratories and reported to the Italian National Institute of Health (NIH) - Italian National Integrated Surveillance System by 20 December 2020<sup>[10]</sup>.

The pandemic has had different intensities and lethality in Italy compared to the rest of Europe. Differences in lethality rates are explained by: demographics, as mortality tends to be higher in older populations with co-morbidities; characteristics of the healthcare system, where there are organisational shortcomings, initial delays in understanding the severity of the emergency, deficits in infection tracking systems, hospitals overwhelmed by admissions, etc.; differences in the number of people tested; and different levels of virus aggressiveness<sup>[11]</sup>.

Italy faced an unprecedented health crisis, with serious shortages of health professionals and difficulties in procuring personal protective equipment. New organisational models had to be



implemented and hospital inpatient facilities had to be rapidly transformed into units suitable for the care of pandemic patients<sup>[12]</sup>.

The NIH weekly bulletin of 28 April 2020 stated that 47.4% of the cases of infection among healthcare personnel were nurses<sup>[13]</sup>.

In Italy<sup>[14]</sup> according to the provincial records, 40 nurses died, 32 of whom with the Covid-19 disease (positive swab), 4 with Covid-related illness (for whom the viral pathology was a favourable factor) and 4 (positive in any manner) for whom the mode of death was suicide<sup>[15]</sup>. A different view of the same phenomenon is reported by the monitoring as of 15 June 2020 conducted by INAIL (Italian National Institute for Insurance against Accidents at Work). INAIL, considering the accident reports referring only to insured workers, certified that there were a total of 236 deaths from Covid-19, of which 40% were healthcare professionals and 61% were nurses. In this complex epidemiological and healthcare framework, healthcare personnel reported the consequences of significant psychophysical stress with experiences and emotions still largely to be explored. Arasli et al. (2020)<sup>[16]</sup> explored experiences during the Covid-19 pandemic through testimonies written by nurses on social media through qualitative research. The study showed a high level of stress among healthcare professionals related to the risk and fear of becoming infected. Labrague et al. (2020)<sup>[17]</sup>, through a quantitative study conducted in a region of the Philippines, highlighted high dysfunctional levels of anxiety in frontline nurses, while recording an increase in their resilience. On the Italian scene, Catania et al. (2020)<sup>[18]</sup> carried out qualitative research involving nurses from all regions of the peninsula. This study highlighted the enormous impact of COVID-19 on nurses, the need to identify new working practices, and highlighted the high-risk nature of nursing, exacerbated by the difficulty in Personal Protective Equipment (PPE) availability. In addition to reporting the high levels of stress experienced by the interviewees, the element of narratives also highlighted the resilience of the nursing community. Qualitative research was conducted by De Vito et al.<sup>[19]</sup>, through the narratives of paediatric doctors and nurses in the paediatric emergency room of



the Regina Margherita hospital. The authors emphasise how much the number of admissions in the paediatric sector had fallen, reflecting profoundly on changes in care, but also on the relationship itself with and between patients.

The results of the study show how the act of describing helped participants to process and understand their experience. Storytelling provided a cathartic means for participants to reformulate the events they experienced, rationalising them and making sense of them. In the Turin landscape, the experiences of nursing students were investigated. Garrino et al. (2021)<sup>[20]</sup>, through a qualitative study, emphasised the changes induced by Covid-19 in nursing education. The need to use distance learning and the impossibility of doing internships during the pandemic period created many difficulties in training students. The narrative approach<sup>[21]</sup> and reflective thinking<sup>[22]</sup> aim to capture the latent aspects and hidden meanings of the complex pandemic reality<sup>[23,24]</sup>.

The aim of the research is to describe the experience of health workers on a Covid ward, exploring their experiences and emotions.

# MATERIALS AND METHODS

## Study design

In this study, a qualitative methodology was used to investigate subjective phenomena, based on the assumption that fundamental truths about reality are rooted in people's lived experiences. This method allows for exploration of experiences by the person who has them, attempting to describe the meanings that the individual creates and gives to that experience, understanding the structure, nature and form, as perceived by the individual<sup>[25]</sup>. This survey aims to understand the experience of nurses and social workers during the first wave in a ward caring for Covid-19 patients, and who are now called upon again to provide the same type of care, in order to find out how the workers in question have responded to a pandemic emergency which, in addition to involving the work aspect, has invaded the personal sphere.



## **Background**

The San Camillo hospital, as a hospital specialising in second-level functional recovery and rehabilitation, provides intensive rehabilitation treatment in the post-acute phase of the illness. The hospital has five departments that fulfil this function.

In November 2020, during the second wave of the pandemic, two wards were dedicated to the care of Covid patients. The health workers of these two wards, defined as 'COVID staff', had to cope with this new situation with various difficulties that have also characterised many healthcare facilities in Italy, but in this second phase they were able to use sufficient and appropriate PPE. The COVID wards of the facility were designed for a maximum capacity of 20 beds and intended for the care of patients coming from the intensive care units of other hospitals and in the sub-acute phase. Other patients in the early stages of the disease came directly from the emergency rooms of local hospitals, which could not cope with all the demand at that time. During admission, the intention was to stabilise the clinical condition and ventilatory support consisted of a Venturi mask or nasal cannulae, not having the tools provided in intensive care, such as assisted ventilation or intubation of the patient. The hospitalisation continued until the swab was negative, although the symptoms had already receded. Few of these patients died in the facility. The research was conducted in only one of the two Covid departments (with the participation of three respondents who worked in the second department, but who had worked sporadic shifts in the Covid department under consideration).

# **Participants**

In this study, nurses and social workers (OSS) working in the Covid ward of the San Camillo hospital in Turin agreed to participate. Participants include the researcher (MS), in the role of observer-participant.



# Mode of data collection

The study was based on a collection of semi-structured interviews consisting of 11 open-ended questions (Box 1) and proposed directly to the persons involved by email<sup>[26,27]</sup>. Respondents participated on a voluntary basis. Non-probabilistic, purposive sampling continued until data saturation, collected between 15 December 2020 and 15 January 2021. The questions for the semi-structured interviews were elaborated with the narrative interview method<sup>[28]</sup> and were chosen through the "SIFA" method, in order to try to explore each sphere of interest regarding Feelings, Ideas, Functions/Activities of the client, Expectations<sup>[29]</sup>.

## Methods of data analysis

For data analysis, the phenomenological method according to Giorgi (2008)<sup>[30]</sup> was used (Box 2). The interviews were read over and over again, seeking personal assessments through a suspension of judgement. Subsequently, an attempt was made to find common areas of meaning describing the most important themes reported by the interviewees<sup>[31,32]</sup>. The analysis was conducted independently by researchers S.M., L.G., V.A. and V.M. They then compared their work using the triangulation method<sup>[33]</sup>. During the analysis, the researchers reflected on their own values and suspended judgements, knowledge and ideas about the phenomenon under study<sup>[34]</sup>.

## **Ethical consideration**

The persons involved voluntarily agreed to answer the interview and signed an informed consent on the use and processing of the data. The research was authorised by the Health Directorate and the General Directorate of the San Camillo Hospital.

## **RESULTS**

Through field research, 12 interviews were collected. Table 1 shows the socio-demographic data of



the participants.

| Participants  | Profession                                     | Gender | Age | Marital status | Number<br>of | Years of<br>work | Years of work<br>at San Camillo | Type of contract       |
|---------------|--|--------|-----|----------------|--------------|------------------|---------------------------------|------------------------|
|               |  |        |     |                | children     |                  |                                 |                        |
| 1             | Nurse  | F      | 25  | Unmarri<br>ed  | 0            | 2                | 2                               | Fixed-term             |
| 2             | Nurse  | F      | 25  | Unmarri<br>ed  | 0            | 1                | 1                               | Maternity replacement  |
| 3             | Nurse  | F      | 23  | Unmarri<br>ed  | 0            | 1                | 1                               | Freelance professional |
| 4             | Nurse  | F      | 27  | Unmarri<br>ed  | 0            | 3                | 1                               | Freelance professional |
| 5             | Nurse  | F      | 28  | Unmarri<br>ed  | 0            | 5                | 5                               | Permanent              |
| 6             | Nurse  | M      | 47  | Married        | 2            | 12               | 11                              | Permanent              |
| 7             | Nurse  | F      | 29  | Unmarri<br>ed  | 0            | 6                | 6                               | Permanent              |
| 8             | Nurse  | M      | 29  | Single         | 0            | 2                | 2                               | Indeterminate          |
| 9             | Nurse  | F      | 24  | Unmarri<br>ed  | 0            | 2                | 2                               | Fixed-term             |
| 10            | OSS  | M      | 42  | Single         | 0            | 15               | 5                               | Permanent              |
| 11            | OSS  | F      | 26  | Unmarri<br>ed  | 0            | 1                | 1                               | Fixed-term             |
| 12            | OSS  | F      | 45  | Married        | 0            | 12               | 6                               | Permanent              |
| OSS=nurse and | OSS=nurse and social workers; M=male; F=female |        |     |                |              |                  |                                 |                        |

**Table 1** - Social and *personal data of participants* 

The average age of those involved is 30, with a minimum age of 23 and a maximum age of 47. All operators were professionally trained in Italy. None have postgraduate or Master's degrees. Several main and recurring themes emerged from the analysis of the interviews. These macro-categories bring us back to the experience of the participants. Terminology as presented and written by the interviewees themselves is reported, outlining the importance of the meanings expressed by them. The following themes emerged: the beginning of the Covid worker's 'journey' and the whirlwind of emotions and feelings that accompanied that (fear, feeling stuck, helpless, powerless, concerns for one's family in relation to the risk of contagion and the fear of infecting oneself and loved ones), the group as a foothold to keep going, a point of strength, union and provider of trust, the awareness of change, the cognition of time and the constructive vision of the experience (table 2).



The start of the Covid worker's 'journey'

The whirlwind of emotions and feelings: (fear, feeling stuck, helpless, powerless)

Concern for families in relation to the risk of contagion and fear of infecting themselves and their loved ones)

Conflict with PPE: distancing, anonymity and protection

The group as a foothold, a point of strength, of union and a provider of confidence

Awareness of change, cognition of time and a constructive view of experience

**Table 2** – *Main themes emerging from the analysis* 

# The start of the Covid worker's 'journey'

The interviews reveal the profound change that occurred in the participants' professional lives at the beginning of the pandemic. Most of them talk about the impossibility of choosing whether to work in a Covid department or not, often indicating it as a decision linked to a sense of duty fulfilment.

[...] "It wasn't really a personal choice to join the Covid team... I happened to be there, and I was probably OK with that." [...] (interview 1)

[...] "I didn't really have a choice in deciding whether I could work closely with Covid-positive patients... So compared to my start in a Covid department, I can't even explain how it came about."
[...] (interview 3)

Participants underline the initial impact they had following the news, accompanied by a set of feelings that were difficult to deal with at the time and to talk about later. They describe thoughts, emotions and sensations and there are often conflicting feelings, accompanied by fear, anxiety and stress.



- [...] "Literally thrown into the deep end... My thoughts were questions. Why? Why? Why? So many questions that had no answers." [...] (interview 8)
- [...] "I'm still trying to figure it out... on the front line in a Covid ward... I wasn't chosen, I found myself there almost by accident." [...] (interview 7)

In the interviews, the theme of travel emerges significantly, as a symbol of uncertainty and restlessness in trying to know and explore unknown places; as well as the theme of battle, almost as if they had to fulfil a destiny already written in their professional profile.

[...] "I didn't feel chosen, I felt enlisted in an impromptu army for an impromptu battle... I was there, so I had to fight... I had the fear and adrenaline of those who leave without knowing the destination and the consequences of their journey." [...] (interview 4)

## A whirlwind of emotions and feelings: fear, feeling stuck, helpless, powerless

Concerning the emotions felt during this long experience by the health workers, many of them found themselves facing different difficulties, multiple fears and feelings, one of the main ones being isolation, not only physical but also psychological.

- [...] "I avoided even the contact allowed by the Decrees, I isolated myself completely, more than was necessary... All you can do is wake up in the morning and wonder when it will end... I would have liked to live fully, not at the mercy of anxiety and worry. [...] (interview 1)
- [...] "I would arrive home drained, feeling nothing but tiredness that muffled all the outside world."
  [...] (interview 2)
- [...] "I see myself as someone who put aside feelings and sensations to face a big battle, so today I don't even remember what I was feeling... We have lost all consciousness, we no longer saw well,



we no longer heard well, we no longer spoke much..." [...] (interview 3)

Respondents write that they feel alone in this battle, misunderstood, stuck and aimless, depersonalised, helpless due to the suits and masks, powerless before an invisible enemy so difficult to defeat.

[...] "When I finish a shift, I feel like I have finished a test under stress... as though I had passed a test... many times I felt like I hadn't made it, as though the ground was sinking from under my feet, other times I felt empty, as though under that suit there was almost nothing left... as if I had failed, as if I hadn't done enough." [...] (interview 4)

[...] "I remember the fear... and the tiredness because I had been alone in facing that new beginning so physically and psychologically intense... The whole condition of isolation puts a lot of pressure on you psychologically... I felt powerless, a nobody before something so big... I felt like a wrapper, a container whose contents had been disposed of along with the protective suit." [...] (interview 5)

## The family and the risk of contagion: the fear of infecting oneself and one's loved ones

A topic that is repeated in almost every narrative is the importance of family affection. This theme is often addressed in the interviews, emphasising the importance that health workers attached to the support given by their loved ones, but at the same time linked to the constant fear of infecting themselves and consequently their families.

[...] "If I get infected will I be sick? And at home? If mum and dad get ill? Who will take care of Granny if we are sick? What if Granny gets sick?" [...] (interview 1)

[...] "I was afraid though, afraid of not being up to it and afraid of infecting myself and my loved ones." [...] (interview 2)



[...] "The biggest fear I had was that I would get worse and that I could infect my partner... that last idea drove me mad." [...] (interview 5)

There was a high level of stress among the interviewees, which, despite everything, also contributed to an increase in attention and precautions regarding safety regulations, the correct use of personal protective equipment and the correct way of disposing of it.

[...] "At the onset, I didn't have tumultuous emotions, it was the people next to me who were really very worried and I honestly experienced their emotion... The first thing I think about when I start my shift is that I must not get sick, so I must do everything I can to avoid infection." [...] (interview 3)

[...] "I try to be focused because you can let your guard down due to tiredness and then risk getting infected." [...] (interview 12)

# Conflict with PPE: distancing, anonymity and protection

The interviews reveal the perceptions of nurses and social workers obliged to wear "all those layers of latex", exploring their experiences in relation to the care provided to their patients on the Covid ward. Nurses and social workers talk of overalls, double gloves, double masks, footwear, goggles and face shields which, while vital for working on Covid wards, have raised barriers between staff and patients.

[...] "A person covered from head to toe without knowing what he looks like or not remembering his name, as if he wasn't human... and all I know of this person are his brown eyes surrounded by a mask and a big suit." [...] (interview 1)

[...] ""Halfway between astronauts and aliens!" [...] (interview 2)



[...] "I never imagined that I would keep my physical and moral distance from a patient in such a way that I could become one of the many operators, just any operator, someone easily replaceable...

I didn't use to feel naked unless wearing a gown, visor and mask, whereas now I do." [...] (interview 3)

[...] ""So many little white men, completely covered by overalls, gowns, masks, gloves and visor, almost clumsy in their movements and practically indistinguishable from each other... What I miss most is being able to show my smile to the patients, free from masks, and to shake their hands, free from those multiple layers of gloves." [...] (interview 5)

[...] "Living diving suits... it's as though there were a thousand barriers, a thousand layers separating us...a gentle caress with double latex gloves is not the same..." [...] (interview 6)

# The group as a foothold for not giving up: strength, unity and trust

From the interviews, it emerges that the group has been a strong point, an important support for the health workers to go on and not give up.

[...] "I have never believed in the motto 'unity is strength' as I do now... in April there were so many brave little soldiers, in November we were one giant soldier...I don't feel alone, never; I feel escorted, I feel that someone is looking out for me as I am looking out for someone else... the working group has become a family... I would get through this as long as I had this team to rely on." [...] (interview 4)

[...] "I am grateful to her for that moment, for understanding me and giving me strength when she was probably also on her last legs. We hugged each other when we left the hospital, amidst tears. I don't think I could have done it without her that day." (Interview 6)

[...] "We have been able to overcome some difficult moments only thanks to our unity. (Interview 7)



According to the interviewees, coping with such a complex period with one's *team* helped to increase cohesion, strengthen group dynamics and was often the driving force needed to cope with stressful situations.

[...] "The wonderful team I have the honour of sharing this experience with has become very cohesive. We all worked together for the same goal on the same road, holding hands, hugging ideally, supporting each other, experiencing the same feelings, falling down and helping each other up." [...] (interview 3)

[...] ""I believe that the greatest strength came from the working group, which I have never before felt close to me, or rather part of me... in the group set up for the Covid emergency, I really found a rock to rely on. We work with common principles, side by side to achieve the same goals. What I perceive between us is harmony, respect and sharing"[...] (interview 5)

#### Awareness of change: time, self-work, constructive view of the experience

What emerges from the interviews is the strength and the desire to take charge of one's own life again, the desire to make it through this pandemic, trying to find a positive side, not to throw everything away, to seize what good can come from this experience. From the words of those interviewed, one can see a devastating past and present, which has affected people greatly, but also a future full of hope.

[...] "I hope to be myself with some more awareness, especially about what was taken for granted before Covid... I'm happy to still feel like myself, to not want to give in to the suffering that Covid forced us to face every day." [...] (interview 2)

[...] ""I worked on myself like we all did...The nurse I loved to be is here somewhere, she is not gone... My job will go back to that wonderful normality I loved, with some more experience, some



scars that won't go away, some indelible memories..."[...] (interview 4)

[...] ""I hope to still be the same, with more experience on my shoulders. Of course, the pandemic has changed everything and everyone, but life goes on and you have to think about facing the next enemy."[...] (interview 8)

[...] ""I hope to see myself proud of what I have done, I hope to have left a good memory in the people I have met and I will be able to say this one is gone too." [...] (interview 12)

#### **DISCUSSION**

The aim of this study was to describe the experience of healthcare workers in a Covid ward, exploring their emotional experiences and attempting to capture the meanings that the individual creates and gives to that experience, understanding the structure, nature and form, as perceived by the individual. This survey collected the experiences of nurses and social and health workers who worked in a ward for the treatment of patients affected by Covid-19, in order to know how they responded to an emergency situation that not only involved the work aspect but also invaded the personal sphere. From the data collected, it emerges that the pandemic is immediately experienced by health workers as insidious, bringing uncertainties and anxiety, emotions and feelings that can be traced back to a scenario reminiscent of a battle. You feel overwhelmed by a storm, you prepare for the arrival of a real 'enemy' [19], you find yourself united by the same feelings, but at the same time alone and ill-prepared, forced to take the to the field with the few weapons available. This describes the whirlwind of emotions, fears, worries, feelings of helplessness, a mixture of negative feelings in which there is rarely any slight hope for the future. In the interviews, all subjects tell of their fears: of becoming sick and infected, of being isolated, of not being ready to face the big changes in the work structure. This issue is dealt with extensively by Catania et al.<sup>[18]</sup> and by De Vito et al.<sup>[19]</sup>, highlighting how the narratives of the nurses, also working in different wards, underline the common theme of the physical and psychological impact that the change in work organisation had



on the same individual workers and on team work. In the study by Arasli et al<sup>[16]</sup>, 'fear' and 'risk' were two of the most frequently used words by nurses in social media during the pandemic. Among the feelings experienced there is certainly no lack of anxiety, which is expressed several times in the narratives considered in this study and is also widely described in the article by Labrague et al.[17]. From the data collected it emerges how the entire pandemic situation forces nurses and social and health workers to create a different way of being workers, a situation that almost imposes a different way of directing the therapeutic relationship no longer mediated by touch, words, reciprocal dialogue and the security of familiar clothing, but hindered by the trappings of a distancing "dress" and by the impossibility of speech that bring out a problematic core of objectification of care. This aspect emphasises how to deal with health emergencies, without at the same time renouncing the humanity of the therapeutic relationship that characterises this profession. All the images described in the interviews are of 'detachment' from one's own body which, within the innumerable protective layers within which it is forced, finds itself taking on a form unknown to the eyes of the subjects themselves. These people are the same as those who performed acts of care, but in doing so they all felt equal and experienced a human closeness made up only of glances. From the narratives of this research, a strong spirit of adaptation and resilience emerges in nurses, aspects also described by Catania et al.<sup>[18]</sup> and Labrague et al.<sup>[17]</sup>. This theme was widely taken up in the interviews, allowing us to outline through these nurses "made of suits and personal protective equipment", an image in which latex and nitrile are transformed into a material capable of absorbing a shock without breaking, to face and overcome a traumatic and extreme event, to give hope in the future. Wu Y. et al. [35] show that doctors and nurses working in Covid wards experienced lower levels of anxiety, depression and burnout than those working in their usual wards, with a response to the pandemic characterised by a high level of adaptation and resilience. The participants of our study emphasised that the team proved to be the most important strength in overcoming daily difficulties within the Covid department. The objectives for which the group meets and works together and the dynamics



of consolidation of the process that forms the working group, from interaction to integration<sup>[35]</sup>, are essentially described in both processes and activities: the group intervenes whenever someone is in difficulty; a hand is always extended towards the other when one finds oneself lost in what should be a known world but has become an unexplored labyrinth. The feeling of belonging to the group is found to be a decisive positive factor also among the students of the article by Garrino et al.<sup>[20]</sup>, which underlines how the comparison between peers and the support provided by peers are a decisive element to deal positively with the practical traineeship experience.

Another important theme that emerged from the interviews was time. A time that sometimes expands, sometimes shrinks, but which must be lived anyway<sup>[19]</sup>. In fact, the impact of the pandemic marked a deep rift between what was before and what would be after. This perception had different effects. On the one hand, it made them feel stuck and unable to imagine the future from such an uncertain present; on the other hand, it allowed them to discover new physical spaces and adopt new or renewed daily habits which helped them to imagine a possible future. The perspectives described are linked to fear, but also to the hope that normality will be re-established, both on the horizon of care and in daily life. These reflections represent an added value that contributes to a greater understanding of oneself and the role that one's experiences played during the emergency. Narratives have been a useful tool for making sense and meaning of the experiences associated with the pandemic experience<sup>[19]</sup>.

#### **CONCLUSIONS**

The research explored the lived experiences of a small group of health workers working in a Covid ward during the pandemic in November 2020. Telling stories was a chance to give shape to the situations experienced, continuing to plan oneself, giving new meaning and significance to one's existence. Narrative and mutual listening practices were recognised as very useful and effective in capturing and understanding meanings, emotions and representations about one's professional role



and wider existential issues. This research provides evidence to improve the strategies to deal with a health emergency by listening to personal experiences and thoughts, by accepting the emotions and feelings felt by the care professionals, experiences and representations that, many times, in these situations the caregiver may struggle to express or, even, prefers to keep hidden under his uniform. It can be concluded that narrative medicine used in care environments, in situations where there is no space and time for the individual, offers the possibility to improve and increase the communication and cooperation skills of all; to develop new knowledge of each operator to improve the relationship with others; to give meaning and value to the experience of care of health workers and help them to process and alleviate, as far as possible, the emotional stress that accompanies them in the difficult path of care.

#### **LIMITATIONS**

Data were collected by sending an interview outline via email. This method was chosen due to the lack of opportunities to conduct the interview due to the national lock-down and to allow the interviewees to express themselves freely and openly without time constraints. this deprived the research of elements concerning the conducting and interaction aspects that usually characterise *face-to-face* interviews.

#### CONFLICTS OF INTEREST AND FUNDING SOURCES

No funding sources were used to support the project. There is no conflict of interest.

#### **DECLARATIONS**

No formal approval by the Local Ethics Committee was required for this study.



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#### Box 1 – Interview outline

- 1. Could you tell me how your adventure in the Covid ward started?
- 2. What was the first thought that came into your mind when you were chosen as Covid-19 worker?
- 3. How do you think your way of working has changed compared to before?
- 4. If you saw yourself through the eyes of a patient, how would you describe yourself?
- 5. How do you feel and what do you think when you finish your shift and leave the hospital?
- 6. And what do you think and feel when you have to start a shift?
- 7. has anything changed in the working group compared to previous months? If so, what?
- 8. Can you tell me an episode that made you think you could deal with all this with your team?

#### Box 2 - Giorgi's method (2008)

- A. Read the whole description of the experience with the aim of making sense of it all
- B. Rereading the descriptions to discover the essences of the experience. Observe every time a transaction takes place in meaning. Make these meaning units or themes abstract
- C. Examine units of meaning for redundancy, clarification or elaboration. Relate units of meaning to each other and to the meaning of the whole
- D. Reflect on the units of meaning and extrapolating the essence of the experience for each participant. Transform each unit of meaning into scientific language



## The influence of mobile app in Glycemic Control and Prevention of Hypoglycemics in Diabetic management: A Systematic Review

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**Introduction.** The use of technology in the treatment of diabetes can facilitate the medium of communication between nurses and clients in data collection to create a comfortable life for patients. The use of mobile health technology in diabetic education is an innovative learning method that can engage patients and influence positive health behaviors.

**Aim.** This study aims to find out the influence of mobile-based education applications in the Haemoglobin A1c control and prevention of hypoglycemia in patients with type 2 diabetes mellitus. **Methods.** Database search for article are from four databases such as Pubmed, Sciencedirect,

Proquest, and Cochrane is limited to the publication of the last ten years from 2010 to 2021 and full text article in English. Authors individually screened the titles and abstracts, then full articles in

order to obtain papers that met inclusion criteria

**Results.** a total of 664 references were found. After duplicates were removed, 391 potentially relevant references remained from the database searches. Eight articles were finally designated as articles to be reviewed and use RCT design. Most studies put a Haemoglobin A1c (HbA1c) as a primary outcomes, and hypoglycemia as a secondary outcomes. Through the use of mobile app, there are reductions in HbA1c which affect the hypoglycemia events in Type 2 DM patients.

**Conclusion.** Mobile application can enhance HbA1c and hypoglycemia control among T2DM patients. Because providing patient education face to face is time-consuming, the use of mobile application may be an effective complement or alternative for healthcare professionals to manage the rapidly increasing number of diabetes patients.

Keywords: Mobile app, Type 2 DM, Glycemic control, Hypoglicemia prevention



#### Introduction

Diabetes mellitus, particularly type 2, is a global health issue in the worldwide. The International Diabetes Federation (IDF) estimated an escalation of diabetes prevalence from 424.9 million in 2017 to about 628.6 million by 2045 [1]. More than 10,3 million people had diabetes mellitus in Indonesia [2]. Ninety percent (90%) of diabetes cases is type 2 diabetes mellitus with characteristics of insulin sensitivity disorders and/or impaired insulin secretion [3]. The prevalence of diabetes mellitus in Indonesia based on doctor's diagnosis in the population aged ≥15 years has increased from 1.5% in 2013 to 2.0% in 2018 [4,5]. Administration of insulin therapy causes the main side effect of hypoglycemia. Another side effect is the immune response to insulin which can lead to insulin allergies or insulin resistance [3]. Hypoglycemia is a condition in which glucose levels in the blood decrease below the value of 70 mg / dl or less [6,7]. The prevalence of hypoglycemia with type II diabetes mellitus patients can reach 70-80%, which has a serious impact on morbidity, mortality, and quality of life [8]. Severe occurrence of hypoglycemia in type 2 diabetes mellitus patients reaches 3-73 episodes per 100 patients annually [6]. A common phenomenon in the clinical practice is that many patients argue that mild hypoglycemia as a consequence of hypoglycemic control [9]. In addition, many patients misunderstand the symptoms of hypoglycemia as a symptom of ketoacidosis, because they need to reduce or delay insulin administration [10]. Patients attempted to lower blood sugar levels without knowing the effects of using the drug where patients may experience severe hypoglycemia as the result. One of the reasons for the lack of patient knowledge about hypoglycemia is the lack of information provided by healthcare professionals [11]. Shreds of evidence have shown that the potential use of smartphone-based technology has helped people with diabetes in self-care management by staying connected with health care providers. Futuristic features are provided with all the ease to understand and use [12,13]. A well-suited App could transform a mobile phone into a medical device helping ease the burden of diabetes, preventing complications, and improving a patient's quality of life. However, an overwhelming number of



products and services are available to patients with diabetes. Patients and providers must recognize the characteristics of these products and services to capitalize on the advantages while avoiding harmful deficiencies [14]. The use of technology in the treatment of diabetes can facilitate the medium of communication between nurses and clients in data collection to create a comfortable life for patients. An important goal of treatment with electronic media is to enable patients the opportunity to maintain effective they education without interruption [12]. Interest in mobile health apps in supporting self-management of health arises because it is easily accessible, portable, low cost, convenient for users, and has a widespread. Furthermore, 50% of smartphone users will have at least one mobile health app [13]. The use of mobile health technology in diabetic education is an innovative learning method that can engage patients and influence positive health behaviors [14]. This review aims to collate and provide evidence related to mobile application for Glycemic Control, and prevention of hypoglycemia of Diabetes Melitus patients.

#### Methods

#### **Design**

This study is a systematic review based on Preferred Reporting Items for Systematic Reviews and Meta-Analyzes (PRISMA). PRISMA is an evidence-based minimum set of items for reporting in systematic reviews and meta-analyses. PRISMA focuses on the reporting of reviews evaluating randomized trials, but can also be used as a basis for reporting systematic reviews of other types of research, particularly evaluations of interventions. Authors must use PRISMA as a guideline and theory underlying aims to help authors improve the reporting of systematic reviews and meta-analyses (PRISMA Statement, 2015).

#### **Eligibility**

Inclusion criteria for this systematic review are (1) adult-elderly patients (18-85 years), (2)



uncomplicated or non co morbid diabetes mellitus patients, and (3) patients who are conscious and cooperative (4) study design that include in this review is randomized control trials (RCT). Exclusion criteria in this systematic review are (1) patients experiencing complications (stroke, heart, kidney), and (2) patients who have dementia and aphasia.

#### Search Methods

Database search for article are from four databases such as Pubmed, Sciencedirect, Proquest, and Cochrane is limited to the publication of the last ten years from 2010 to 2021 and full text article in English. Keywords used in the article search of all databases are combination of "diabetes mellitus" OR "Type 2 DM" AND "glycemic control" OR "Hypoglicemia prevention" OR "HbA1c" AND "health education" AND "m-health" OR "Mobile app". The next step after the articles that meet the criteria are collected is to analyze and form the articles according to the specified inclusion—and exclusion criteria. The article search process was carried out in August 2021. The article search uses keywords that have been determined by the researchers and limits the inclusion and exclusion criteria. The data obtained are then selected one by one by the researchers to determine the suitability of the articles desired by the researchers and delete the same articles or those that do not fit the criteria. After getting the articles according to the researchers, the articles are analyzed one by one and grouped to get the results. The next step is to discuss based on the points obtained from the selection results.

#### Critical appraisal

The included quantitative studies were appraised using the McMaster Critical Review Form for quantitative studies [18]. The critical appraisal process was undertaken independently by the two authors. Discrepancies in scoring were then resolved through discussions until consensus was achieved.



There are 13 question items that can be answered with yes, no, and not addressed options. Scores are given as a percentage, and one point for each question item if available. 90% were categorized as high quality, 70% medium, and low quality for the rest.

#### **Data Abstraction**

Two authors independently reviewed the abstracts of studies retrieved from the database Search and read the full-text of potentially relevant articles. For studies that met the inclusion criteria, data extraction was independently conducted by two investigators using our data extraction tool adapted from existing guidelines and other review articles of mobile application for DM [19,20]. Using this tool we extracted the general and mobile app features of the papers including the outcome, study design, characteristics of the intervention, evaluation method and main findings. Disagreements in data extraction were solved by a third investigator.

#### **Data Analysis/ Synthesis**

Data of the studies included were synthesized thematically in order to understand the effectiveness of mobile application. Thematic analysis involves discovering, interpreting and reporting patterns and clusters of meaning within the data. Using this frame-work and by reading the included articles several times, themes were identified. Subsequently, these themes were further examined for their similarities, differences and contradictions. The subject matter of the findings from the quantitative studies was examined, and the resulting information was placed under the qualitative themes. This integration of quantitative findings to the qualitative themes was completed by the first author. The second author reviewed the matched themes and quantitative studies. Any disagreement was resolved through mutual discussion. Due to the heterogeneity and insufficient number of the studies included, we could not conduct meta-analyses.



#### Results

#### **Search Results**

Combining the output of the searches in the various databases, a total of 664 references were found. After duplicates were removed, 391 potentially relevant references remained from the database searches. 283 articles removed by reasons of irrelevant, review/report, not full text, book chapter. Eight articles were finally designated as articles to be reviewed. PRISMA flowchart for Study selection can be presented in Figure 1.

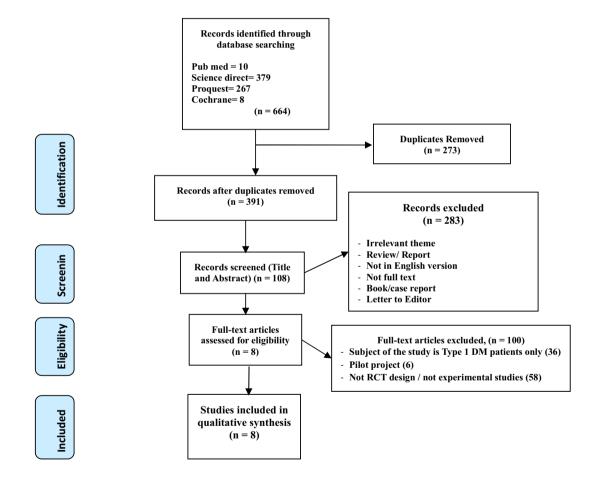


Figure 1. PRISMA flowchart for Study selection

The main focus of this systematic literature review is the effects of mobile app on hypoglycemia prevention. However, to optimize the interpretation of these effects, we will first clarify the



methodological quality and characteristics of the studies, as well as the characteristics of the mobile app under review. The authors developed tables for data analysis with the type of diabetes addressed in the review article, the types of technology used for the intervention along with outcomes measured. The most common health outcome measure was hemoglobin A1c (A1c), and hypoglycemia may present in secondary outcome. This shared data element allowed comparison between the varying interventions addressed in these reviews.

In Table 1 we reported the articles included in our study.

| Author,<br>year,<br>Country    | Outcome  | Study<br>design,<br>participant                       | Intervention  | Evaluation method  | Findings  |
|--------------------------------|--|---|---|--|---|
| Holmen et al., 2014, Norway    | Primary: Change in HbA1c Secondary: self- management, Lifestyle changes, Quality of life | RCT, 151 participants divided into 3 groups           | - 1-year intervention to increase self-management comprised of 3 intervention groups: the Few Touch Application (FTA) intervention group, the FTA with health counseling (FTA-HC) intervention group, and the control group | Self-reported, The Health Education Impact Questionnaire (heiQ), SF-36 | -The change in HbA1c level did not differ significantly between the 3 groups after 1 yearHbA1c level declined within all groups   |
| Waki Et<br>al., 2014,<br>Japan | Lifestyles<br>changes, HbA1c   | RCT, 54<br>type 2<br>diabetes<br>more than 5<br>years | - 3-month intervention - the DialBetics group received a smartphone, NFC-enabled glucometer, and Bluetoothenabled BP monitor, and pedometer with a unique communicator  | Questionnaire  | HbA1c and FBS values declined significantly in the DialBetics group: HbA1c decreased an average of 0.4% compared with an average increase of 0.1% in the non-DialBetics |



|                         |                               | DCT 162                                 | that transmitted the readings by wireless network to the DialBetics server - Participants in the non- DialBetics group would continue self- care regimen without any devices  |   | group (P= .015)  |
|-------------------------|-------------------------------|---|---|---|--|
| Quinn et al., 2011, USA | Change in glycated hemoglobin | RCT, 163 type 2 diabetes for ≥ 6 months | - Group 1: control— usual care (UC), group 2: coach- only (CO), group 3: coach PCP portal (CPP), and group 4: coach PCP portal with decision-support (CPDS) - The intervention was a patient- coaching system and provider clinical decision support - Patients received a One Touch Ultra 2 glucose meter and supplies. Patients in the three active treatment groups received identical study materials: mobile phones, 1-year un limited data and service plan, study mobile diabetes management | Self-reported in mobile phone application | - Participants had a mean baseline glycated hemoglobin of 9.4% - the CPDS patients had a significantly greater decrease in m ean glycated hemoglobin than the UC patients (P 0.001) - CO and CPP mean glycated hemoglobin levels decreased over 12 monthsbthan UC (CO, P =0.02; - CPP, P=0.45) |



|            |                 |             | Ω 1                         | <u> </u>       |                 |
|------------|-----------------|-------------|-----------------------------|----------------|-----------------|
|            |                 |             | software, and access to the |                |                 |
|            |                 |             | web-based                   |                |                 |
|            |                 |             | patient portal.             |                |                 |
| Franc et   | The mean        | RCT, 665    | - Arm 1 (standard           | Classification | - A significant |
| al., 2020, | change in       | patients of | care), arm 2                | of             | and             |
| France     | HbA1c from      | type 1 and  | (DIABEO                     | Hypoglycemia   | meaningful      |
|            | baseline to 12  | type 2      | alone), and arm             | Adjudication   | reduction of    |
|            | months          | diabetes    | 3 (DIABEO +                 | Committee      | HbA1c           |
|            |                 | with        | telemonitoring              |                | versus          |
|            |                 | intensive   | delegated by the            |                | standard care   |
|            |                 | insulin     | diabetologists to           |                | after 12        |
|            |                 | therapy     | a nursing staff)            |                | months of       |
|            |                 |             | - A reference               |                | follow-up:      |
|            |                 |             | nurse initiates             |                | mean            |
|            |                 |             | the patient to              |                | difference -    |
|            |                 |             | the use of the              |                | 0.41% for       |
|            |                 |             | DIABEO app                  |                | arm 2—arm 1     |
|            |                 |             | on his                      |                | (P = 0.001)     |
|            |                 |             | smartphone.                 |                | and - 0.51%     |
|            |                 |             | The patient                 |                | for arm 3       |
|            |                 |             | enters relevant             |                |                 |
|            |                 |             | data (glycemia,             |                |                 |
|            |                 |             | physical                    |                |                 |
|            |                 |             | activity, and               |                |                 |
|            |                 |             | ingested                    |                |                 |
|            |                 |             | carbohydrates) and DIABEO   |                |                 |
|            |                 |             | calculates the              |                |                 |
|            |                 |             | insulin dose (an            |                |                 |
|            |                 |             | eventual dose               |                |                 |
|            |                 |             | adaptations).               |                |                 |
|            |                 |             | - Intervention              |                |                 |
|            |                 |             | conducted in 12             |                |                 |
|            |                 |             | months                      |                |                 |
| Xu et al., | The primary     | RCT, 89     | - Control group: a          | the summary    | the HbA1c in    |
| 2021,      | outcome was     | patients    | face-to-face                | of diabetes    | the             |
| China      | diabetic        |             | individualized              | self-care      | experimental    |
|            | symptom scores  |             | health education            | activities     | group           |
|            | Secondary:      |             | was conducted               | (SDSCAs),      | decreased       |
|            | blood glucose   |             | for each patient            |                | significantly   |
|            | level including |             | for 4 times, 30             |                | more than the   |
|            | fasting blood   |             | min each time               |                | control group   |
|            | glucose, 2-h    |             | within 4 days               |                | after           |
|            | postprandial    |             | - Experimental              |                | intervention (P |
|            | blood glucose   |             | group: Patients             |                | < 0.05)         |
|            | (2 hPG), and    |             | in the                      |                |                 |
|            | glycated        |             | experimental                |                |                 |
|            | hemoglobin      |             | group were                  |                |                 |
|            | (HbA1c) at      |             | required to                 |                |                 |



|                     | baseline and 6                 |                  | install the   |              |                       |
|---------------------|--------------------------------|------------------|---|--------------|-----------------------|
|                     | months after                   |                  | software and  |              |                       |
|                     | intervention                   |                  | individualized  |              |                       |
|                     | 111101 ( 01111011              |                  | self-   |              |                       |
|                     |                                |                  | management  |              |                       |
|                     |                                |                  | programs based  |              |                       |
|                     |                                |                  | on TCM theory.  |              |                       |
|                     |                                |                  | participants  |              |                       |
|                     |                                |                  | were reminded   |              |                       |
|                     |                                |                  | to submit their   |              |                       |
|                     |                                |                  | management  |              |                       |
|                     |                                |                  | status including  |              |                       |
|                     |                                |                  | food intake,  |              |                       |
|                     |                                |                  | exercise, blood   |              |                       |
|                     |                                |                  | glucose   |              |                       |
|                     |                                |                  | readings, mental  |              |                       |
|                     |                                |                  | status to the   |              |                       |
|                     |                                |                  | "interactive  |              |                       |
|                     |                                |                  | follow - up"  |              |                       |
|                     |                                |                  | module every  |              |                       |
|                     |                                |                  | day   |              |                       |
|                     |                                |                  | - All the   |              |                       |
|                     |                                |                  | participants  |              |                       |
|                     |                                |                  | were followed   |              |                       |
| 771                 | TEI .                          | D.CT 104         | up for 6 months   | X7 11 1      | .1                    |
| Zhang et            | The primary                    | RCT, 194         | - Group A:  | Venous blood | - the mean            |
| al., 2019,<br>China | outcome was                    | with type 1 or 2 | received usual  | measurement  | HbA1c levels          |
| Cillia              | glucose control, including the | or 2<br>diabetes | care and did not install Welltang   |              | in groups A, B, and C |
|                     | changes (from                  | (aged 18-65      | on their  |              | were 7.80%            |
|                     | baseline to                    | years)           | smartphone.   |              | (SD 1.14%),           |
|                     | months 3 and 6)                | y cars)          | They learned  |              | 8.04% (SD             |
|                     | in the HbA1c                   |                  | diabetes-related  |              | 1.38%), and           |
|                     | level. The                     |                  | knowledge and   |              | 7.57% (SD             |
|                     | secondary                      |                  | skills by self-   |              | 1.18%)                |
|                     | outcomes                       |                  | learning and  |              | -1-1/0)               |
|                     | included the                   |                  | summarizing,  |              |                       |
|                     |                                |                  |   |              |                       |
|                     | changes in FPG,                |                  | and adopted   |              |                       |
|                     | body weight,                   |                  | and adopted lifestyles and  |              |                       |
|                     | body weight,                   |                  |   |              |                       |
|                     |                                |                  | lifestyles and<br>behaviours<br>voluntarily.  |              |                       |
|                     | body weight,                   |                  | lifestyles and<br>behaviours<br>voluntarily.<br>- Group B:  |              |                       |
|                     | body weight,                   |                  | lifestyles and behaviours voluntarily Group B: requested to   |              |                       |
|                     | body weight,                   |                  | lifestyles and behaviours voluntarily Group B: requested to install Welltang  |              |                       |
|                     | body weight,                   |                  | lifestyles and behaviours voluntarily Group B: requested to install Welltang on their   |              |                       |
|                     | body weight,                   |                  | lifestyles and behaviours voluntarily Group B: requested to install Welltang on their smartphone.                               |              |                       |
|                     | body weight,                   |                  | lifestyles and behaviours voluntarily Group B: requested to install Welltang on their smartphone. They learned                  |              |                       |
|                     | body weight,                   |                  | lifestyles and behaviours voluntarily Group B: requested to install Welltang on their smartphone. They learned diabetes-related |              |                       |
|                     | body weight,                   |                  | lifestyles and behaviours voluntarily Group B: requested to install Welltang on their smartphone. They learned                  |              |                       |



|            |                                   |              | the one            |                   |                |
|------------|-----------------------------------|--------------|--------------------|-------------------|----------------|
|            |                                   |              | the app, including |                   |                |
|            |                                   |              | glycemic           |                   |                |
|            |                                   |              | control, diet,     |                   |                |
|            |                                   |              | , , ,              |                   |                |
|            |                                   |              | exercise,          |                   |                |
|            |                                   |              | medication, and    |                   |                |
|            |                                   |              | the use of         |                   |                |
|            |                                   |              | insulin. 1         |                   |                |
|            |                                   |              | clinician          |                   |                |
|            |                                   |              | involved.          |                   |                |
|            |                                   |              | - Group C:         |                   |                |
|            |                                   |              | received           |                   |                |
|            |                                   |              | interactive        |                   |                |
|            |                                   |              | management         |                   |                |
|            |                                   |              | online with 1      |                   |                |
|            |                                   |              | dietician and 1    |                   |                |
|            |                                   |              | health manager     |                   |                |
| Sun et     | Glycemic                          | RCT, 91      | - the intervention | Physical          | - the HbA1c    |
| al., 2019. | control,                          | patients of  | group were         | examination,      | level in the   |
| China      | treatment                         | Type 2 DM    | provided           | blood             | intervention   |
|            | adherence, the                    | 1) p = 2 1.1 | training to        | biochemical       | group was      |
|            | rate of                           |              | independently      | tests, follow-    | significantly  |
|            | occurrence of                     |              | use the mHealth    | up clinic visits. | lower than     |
|            | adverse events                    |              | management         | Questionnaire     | that at        |
|            |                                   |              | _                  | for satisfaction  | baseline       |
|            | (hypoglycemia), and satisfaction. |              | app and upload     |                   |                |
|            | and satisfaction.                 |              | the glucometer     | measurement.      | (6.84% [SD     |
|            |                                   |              | data, which was    |                   | 0.765%]        |
|            |                                   |              | then               |                   | - vs 7.84% [SD |
|            |                                   |              | automatically      |                   | 0.73%],        |
|            |                                   |              | transmitted to     |                   | P<.001) and    |
|            |                                   |              | the medical        |                   | that in the    |
|            |                                   |              | server             |                   | control group  |
|            |                                   |              | - the control      |                   | at 6 months    |
|            |                                   |              | group received     |                   | (6.84% [SD     |
|            |                                   |              | a free             |                   | 0.765%] vs     |
|            |                                   |              | glucometer and     |                   | 7.22% [SD      |
|            |                                   |              | were followed      |                   | 0.87%],        |
|            |                                   |              | up through         |                   | P=.02). The    |
|            |                                   |              | conventional       |                   | extent of      |
|            |                                   |              | outpatient clinic  |                   | decrease in    |
|            |                                   |              | appointments       |                   | HbA1c level    |
|            |                                   |              | Tr.                |                   | from baseline  |
|            |                                   |              |                    |                   | level in the   |
|            |                                   |              |                    |                   | intervention   |
|            |                                   |              |                    |                   | group was      |
|            |                                   |              |                    |                   | more than      |
|            |                                   |              |                    |                   | that in the    |
|            |                                   |              |                    |                   | control group  |
|            |                                   |              |                    |                   |                |
|            |                                   |              |                    |                   | (1.07% [SD     |
|            |                                   |              |                    |                   | 0.89%] vs      |



|                         |                     |                                  |   |            | 0.62%<br>[SD1.00%],<br>P=.045  |
|-------------------------|---------------------|----------------------------------|---|------------|--|
| Quinn et al., 2016, USA | The change in HbA1c | RCT, 118 patients with Type 2 DM | - the control group were cared for as usual under the direction of their primary care physician. Patients in the intervention group received a patient coaching system (PCS) and provider clinical decision support - The PCS included a mobile diabetes management software application (MDMA), which allowed patients to enter diabetes self-care data (blood glucose values, carbohydrate intake, medications, and other diabetes management information) on a mobile phone and receive automated, real-time messages that were educational, behavioral, motivational, and specific to the entered data. | Blood test | - Among older patients, HbA1c changed by -1.8% (95% confidence interval [CI] = [-2.4, -1.1]) in the intervention group and -0.3% (95% CI = [-0.9, 0.3]) in the control group over 12 months Among younger patients, HbA1c changed by -2.0% (95% CI = [-2.5, -1.5]) in the intervention group and -1.0% (95% CI = [-1.6, -0.4]) in the control group over 12 months |

 Table 1. Data extraction of studies included



#### The result of Critical review

The results of the critical appraisal of the studies are presented in Table 2, respectively. The data that contributed to the generation of these themes are presented narratively in the following results subsection, with the appropriate source references identified.

|                               | Dolm<br>en et | Waki<br>et al., | Quinn et al., | Franc et al., | Xu et al.,   | Zhang et al., | Sun et al., | Quinn et al., |
|-------------------------------|---------------|-----------------|---------------|---------------|--------------|---------------|-------------|---------------|
|                               | al.,          | 2014            | 2011          | 2020          | 2021         | 2019          | 2019        | 2016          |
| Study purpose                 |               |                 |               |               |              |               |             |               |
| Was the purpose clearly       | $\sqrt{}$     |                 |               | V             |              |               | V           |               |
| Literature                    |               |                 |               |               |              |               |             |               |
| Was relevant background       | $\sqrt{}$     |                 |               |               |              |               |             |               |
| Sample                        |               |                 |               |               |              |               |             |               |
| Was the sample described in   | $\sqrt{}$     |                 |               | $\sqrt{}$     |              | $\sqrt{}$     | $\sqrt{}$   | $\sqrt{}$     |
| Was the sample size           |               |                 |               | $\sqrt{}$     |              |               | $\sqrt{}$   | $\sqrt{}$     |
| Outcomes                      |               |                 |               |               |              |               |             |               |
| Were the outcome measures     | $\checkmark$  | $\checkmark$    |               |               | $\checkmark$ | $\checkmark$  |             |               |
| Were the outcome measures     | $\checkmark$  | $\checkmark$    |               |               | $\checkmark$ | $\checkmark$  |             |               |
| Intervention                  |               |                 |               |               |              |               |             |               |
| Intervention was described in | $\checkmark$  | $\sqrt{}$       |               | $\sqrt{}$     | $\checkmark$ | $\checkmark$  | $\sqrt{}$   | $\sqrt{}$     |
| Contamination was avoided?    | NA            | NA              | NA            | NA            | NA           | NA            | NA          | NA            |
| Co-intervention was           | NA            | NA              | NA            | NA            | NA           | NA            | NA          | NA            |
| Results                       |               |                 |               |               |              |               |             |               |
| Results were reported in      |               |                 |               |               |              |               |             |               |
| Were the analytical methods   | <b>V</b>      |                 | <b>V</b>      | V             |              | <b>V</b>      | V           | $\sqrt{}$     |
| Clinical importance was       | <b>V</b>      |                 | NA            | V             |              | <b>V</b>      | V           |               |
| Drop-outs were reported?      | NA            | NA              | NA            | V             |              | NA            | NA          |               |
| Conclusions and implications  |               |                 |               |               |              |               |             |               |
| Conclusions were appropriate  | $\sqrt{}$     | $\sqrt{}$       | <b>V</b>      | <b>V</b>      | $\sqrt{}$    | $\sqrt{}$     | √           | <b>V</b>      |
| given the study methods and   |               |                 |               |               |              |               |             |               |
| Fleiss Kappa                  | 0.755         | 0.567           | 0.806         | 0.409         | 0.409        | 0.755         | 0.755       | 0.451         |

Table 2. Critical review for Quantitative studies included

Critical appraisal of quantitative research studies: As outlined in Table 2, all of the studies had a clear purpose and relevant literature reviews. All of the studies reported appropriate conclusions, given their study purpose. Table 2 shows the value of Cohen's kappa coefficient in each article with a range of 0.41 to 0.806 with a moderate to strong category. This coefficient is the result of two reviewers who evaluate each article separately.



#### **Study Characteristics**

Most of the selected reviews used research from locations around the globe. Articles that meet the inclusion criteria come from several countries including China [21–23], USA [24,25], Norway [26], Japan [27], and France [28]. The mean age range reported was from 38 to 68 years old. Duration of the intervention was 3 months [27], 6 months [21,22,26], 9 months [23], and 12 months [24,25,28]. The number of participants involved in the study was in the range of 54 to 665 patients divided into intervention and control groups.

#### **Outcomes Measured, Primary Focus**

#### **Primary outcomes**

Change in HbA1c level after 1 year was chosen as the primary outcome because it is the main target measure when treating diabetes and is frequently used when evaluating interventions. HbA1c data were collected through the GPs and were assessed primarily with the Siemens DCA Vantage Analyzer a maximum of 2 weeks before or after the follow-up to reduce measurement bias [26]. In the study of Waki and colleague, HbA1c as a primary outcome was measured from baseline to 3-month follow-up for each patient with an intention-to-treat analysis in intervention and control groups [27].

The primary outcome of Quinn [25] study was change in glycated hemoglobin comparing control usual care (UC) and maximal treatment (Coach primary care providers portal with decision support (CPDS) at baseline versus 12 months. Medical chart reviews were used to ascertain patient data. For patients without a glycated hemoglobin within 4 months of the desired measurement, a glycated hemoglobin test was offered at no charge at baseline to determine eligibility and at 12 months. At baseline, glycated hemoglobin was measured using one device, the Bayer DCA 2000, by trained staff blinded to patient group assignment. At follow-up, if glycated hemoglobin was not ascertained within 14 days of the 12-month time point, reminders were provided to patients and physicians to



complete the test. Glycated hemoglobin level at intermediate time points (3, 6, and 9 months) was collected from patients' medical charts [24,25].

Franc et al. determined the primary outcomes of their study was the mean change in HbA1c from baseline to 12 months (primary endpoint), and the occurrence of hypoglycemia. An independent "Hypoglycemia Adjudication Committee" validated the classification of all declared hypoglycaemic episodes. A severe hypoglycemic episode means that the patient required the indispensable assistance of a third person. A symptomatic hypoglycemic episode refers to those symptoms of hypoglycemia associated with rapid recovery after self-administration of sugar [28]. The primary outcome in Xu et al study [22] was diabetic symptom scores. It was assessed by the diabetes symptom grading and quantitative scale according to the Guidelines for the Clinical Research of Chinese Medicine New Drugs. Secondary outcome was blood glucose level including fasting blood glucose, 2-h postprandial blood glucose (2 hPG), and glycated hemoglobin (HbA1c) at baseline and 6 months after intervention. Serum HbA1c level reflects a patient's blood glucose concentration during the previous 2–3 months, so it was taken into consideration as an essential indicator [22].

The primary outcome in Zhang et al. study [29] was glucose control, including the changes (from baseline to months 3 and 6) in the HbA1c level. The major adverse event was hypoglycemia. Hypoglycemia was defined as  $BG \le 3.9 \text{ mmol/L}$  [21].

In the Sun study, there were intervention and control groups. Primary outcome was self-administered blood glucose level. HbA1c level was measured at 3 and 6 months [23].

The primary outcome of Quinn study [24] was the change in HbA1c (% of total hemoglobin) in the control group versus in the intervention group, at baseline versus at 12 months. HbA1c levels were recorded at baseline and at 3, 6, 9, and 12 months. Patient data were retrieved from medical charts [24].



#### **Intervention Features**

We will describe a mobile application intervention based on each of the studies that we included in this review. Holmen et al., [26]: To increase self-management comprised of 3 intervention groups: the Few Touch Application (FTA) intervention group, the FTA with health counseling (FTA-HC) intervention group, and the control group. The FTA-HC group received health counseling for the first 4 months of the project period. The health counseling was based on the transtheoretical model of stages of change and a problem-solving model, and used motivational interviewing as a counseling technique. The health counseling in the present study was part of the mHealth intervention.

Waki et al., [27]. DialBetics is composed of 4 modules. First is the data transmission module: patients' data—blood glucose, blood pressure, body weight, and pedometer counts. Second is the evaluation module: data are automatically evaluated following the Japan Diabetes Society (JDS) guideline's targeted values. Third is the communication module: about meals, and advice on lifestyle modification. Fourth is dietary evaluation: patients' photos of meals are sent to the server.

Quinn et al., [25]. The mobile software allowed patients to enter diabetes self-care data (blood glucose values, carbohydrate intake, medications, other diabetes management information) on a mobile phone and receive automated, real-time educational, behavioral, and motivational messaging specific to the entered data. The patient web portal augmented the mobile software application and consisted of a secure messaging center (for patient-provider communication), personal health record with additional diabetes information (e.g., laboratory values, eye examinations, foot screenings), learning library, and logbook to review historical data.

Franc et al., [28]. A reference nurse initiates the patient to the use of the DIABEO app on his smartphone. The patient enters relevant data (glycemia, physical activity, and ingested carbohydrates) and DIABEO calculates the insulin dose (an eventual dose adaptations). These data are sent every 2 h to a platform that is continuously visible by the reference nurse and the



investigator.

Xu et al., [22]. The smartphone app for diabetes management was composed of 4 modules: syndrome differentiation, body differentiation and health preservation, thesaurus, and interactive follow-up. A reminder message would be received if the patients forget to complete that in time. The diabetes educators can track the data from the app and provide specific guidance and suggestions for the clients.

Zhang et al., [21]. Welltang app mainly comprises 4 parts: education, self-management (including records of SMBG, diet, exercise, medication, body weight, and other diabetes data), patient community, and communication between patients and clinicians. For clinicians, Welltang mainly provided the real-time uploading of data from patients.

Quinn et al., [24]. Mobile diabetes management software application (MDMA) allowed patients to enter diabetes self-care data (blood glucose values, carbohydrate intake, medications, and other diabetes management information) on a mobile phone and receive automated, real-time messages that were educational, behavioral, motivational, and specific to the entered data.

Sun et al., [23]. Patients uploaded the glucometer data to the mHealth management app which was then automatically transmitted to the medical server (glucometer was connected to the mobile phone via Bluetooth). The medical teams sent medical advice and reminders to patients to monitor their glucose levels via the personal messaging app or telephonically every 2 weeks.

#### **Discussion**

This systematic review provides an overview of studies on mobile applications in improving HbA1c and hypoglycemic control among T2DM patients. The highest decrease in HbA1c was 1.9% which is relatively high compared to several previous studies, which found a decrease in HbA1c of 0.49% [30] and 0.51% [31]. There was no subgroup analysis in studies involving patients in different age groups. In general, it can be concluded that mobile application interventions can provide the same



benefits for younger (<55 years) or older (≥55 years) T2DM patients. It is inconsistent with findings from a previous systematic review [30], which suggested that ST interventions were more effective for younger T2DM patients than older patients. The mobile applications in the included studies are complex and generally include more than one component. Almost all studies evaluate mobile applications related to lifestyle modification and self-monitoring of blood glucose. Therefore, it is logical to conclude that a decrease in HbA1c is associated with improving the patient's lifestyle. Although quality improvement programs are usually multi-component, they are more oriented towards targeting changes in health care provider behavior or service delivery models [32]. Interventions using mobile applications have a stronger focus on empowering patient behavior change. A systematic review Barreira et al., [33] showed that exercise effectively reduced HbA1c. Of the four included studies, which have included a component of exercise adherence monitoring [23,26,27], this suggests that a mobile application may be an effective adjunct to controlling HbA1c, or It is more common to enhance lifestyle modification efforts among type 2 DM patients. These studies also suggest considering the mobile application as a complementary intervention that can be used in diabetes self-care strategies more effectively through lifestyle modification and selfmonitoring blood glucose. In the included studies, self-monitoring of blood glucose was also included as part of a mobile application intervention, while its effectiveness in controlling DM was uncertain.

A previous systematic review study Xu et al., [34] concluded that SMBG only contributed to a 0.46% decrease in HbA1c. Available evidence suggests that SMBG can promote self-management, increase medication adherence rates, and improve the patient's ability to detect hypoglycemia [35]. However, the UK National Institute for Health and Care Excellence guidelines state that SMBG is not recommended as part of routine DM management but should be considered in subgroups of patients, such as those receiving insulin therapy and patients prone to hypoglycemia [36]. Current clinical practice guidelines recommend close monitoring of HbA1c and titration of drug therapy



instead [37]. It was difficult for us to find relevant literature on mobile applications to reduce the risk of hypoglycemia in both type 1 and type 2 DM patients. Several studies that we included in this review made hypoglycemia a secondary outcome. The results obtained from the two studies stated that there was no significant difference between the intervention group and the control group. Reports of signs and symptoms of hypoglycemia occurred only once or twice in 1 year of follow-up [25,28]. However, post hoc analyses of the Action to Control Cardiovascular Risk in Diabetes (ACCORD) trial indicated an increased hypoglycemia risk in type 2 diabetic participants with poorer glycemic control than subjects with more desirable HbA1c levels, irrespective of assigned treatment group [38]. Based on this statement, it can be concluded that from all studies included in this review, the mobile application can provide an effect on controlling hypoglycemia levels in Type 2 DM patients, although it is not clearly stated how the mechanism is. Little is known about the relationship between glycemic control and hypoglycemia in the usual care setting, where clinical decision-making about treatment intensity occurs and is modified throughout a patient's life [39]. Based on the two studies included in this review, it appears that there is no significant effect of the use of mobile phone applications on the quality of life of people with diabetes. The possible cause of no significant change in the quality of life before and after using the application is the age of the participants, most of which are in the elderly who feel less interested in using technology, especially smartphone-based [26]. The elderly need more intensive guidance regarding the use of technology applications, usually the elderly ask to be accompanied by family members or people who care for them. For the elderly who feel the exhaustion of their illness, they often hand over the responsibility to the people who take care of them [40,41].

#### Conclusion

In conclusion, mobile application can enhance HbA1c and hypoglycemia among T2DM patients.

Because providing patient education face to face is time-consuming, the use of mobile application



may be an effective complement or alternative for healthcare professionals to manage the rapidly increasing number of diabetes patients. Because providing patient education face to face is time-consuming, the use of mobile application as an educational media may be an effective complement or alternative for healthcare professionals to manage the rapidly increasing number of diabetes patients. The evidence suggests that organizations, diabetes educators, policy makers, and payers should consider these solutions in the design of diabetes self-management education and support services for population health and value-based care models. With the widespread adoption of mobile phones, digital health solutions that incorporate evidence-based, behaviorally designed interventions can improve the reach of and access to diabetes self-management education and ongoing support.

#### Limitation

We have identified several limitations in this study, including limited access to several good-quality databases, which are expected to provide broader search results. In addition, studies that matched our inclusion criteria were also very limited with regard to hypoglycemic control. We also considered potential bias related to different intervention/app, duration of intervention, and the limited numbers of RCTs included. Also, in the search strategy, some important databases are missing.

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#### **Competing interests statement**

There are no competing interests for this study.



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