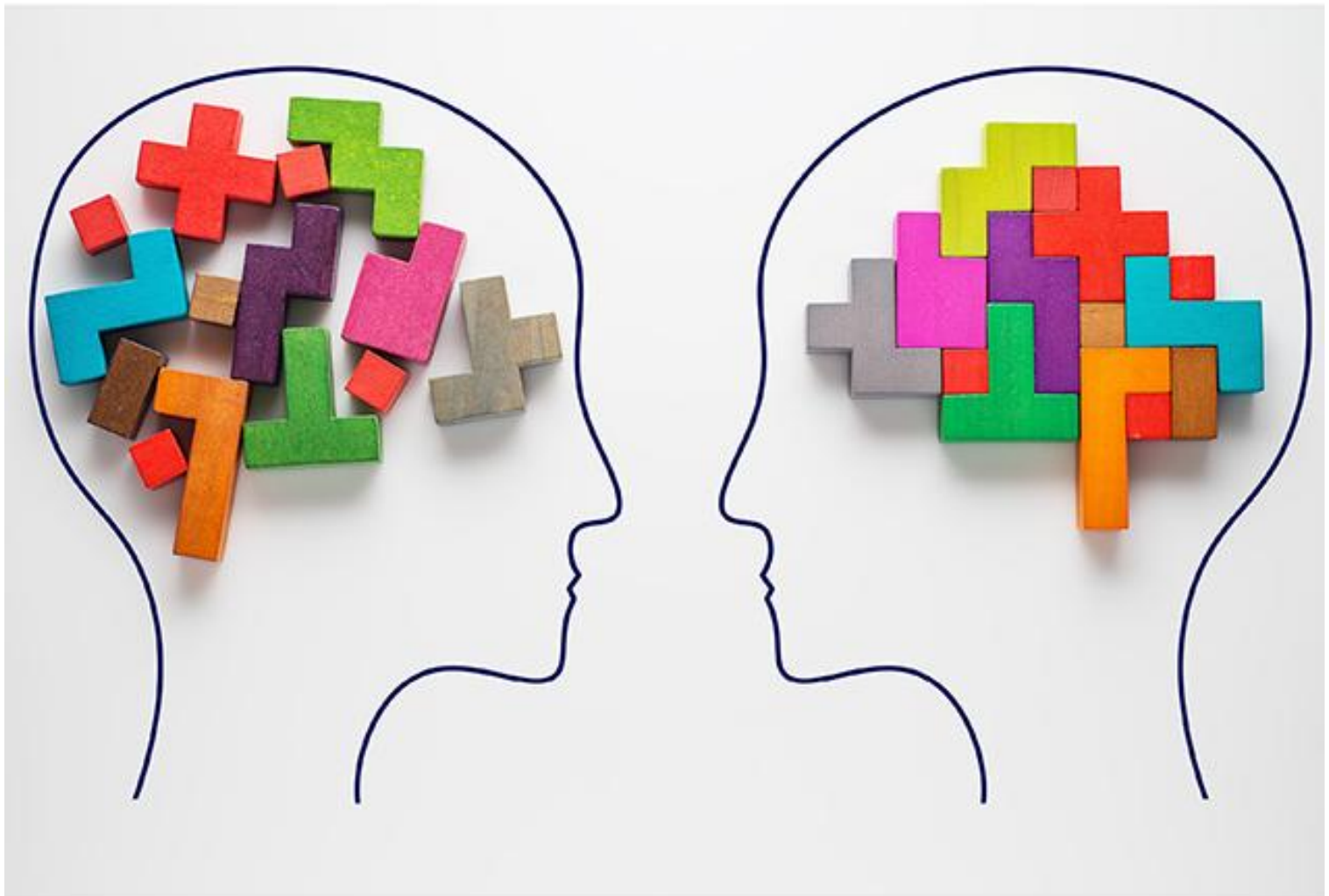


# Perspectives in Public Health

- Workplace wellbeing
- Organisational injustice from the COVID-19 pandemic
- Differences in the impact of precarious employment on health across population subgroups
- Using social media for smoking cessation interventions

*A journal of the Royal Society for Public Health*

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VISION, VOICE AND PRACTICE

## 2021 – Global challenges and changes

**Theo Stickley**

Deputy Editor, *Perspectives in Public Health*

Welcome to the first issue of *Perspectives in Public Health* in this new year. It is perhaps for the first time in a generation that a particular year will go down in history as a year that public health eclipsed all other global news. Let us hope that 2021 will bring some kind of manageable resolution to the COVID-19 crisis that has devastated communities and many lives of individuals around the world.

Here in the UK, the pandemic has also disrupted how public health is managed and delivered at a national and local level. Government policy of nationally commissioning large private companies to deliver services, including contact tracing, has been challenged by those responsible for health protection services at a regional and local level. In the aftermath of the pandemic, serious attention will need to be given to rebuilding the meaning, function and practice of health improvement both nationally and regionally. As with other academic journals, *Perspectives in Public Health* will continue to publish current research and practice reports regarding the pandemic as speedily and accurately as possible, as well as continuing to update on the work of the Royal Society for Public Health (RSPH) and encourage development and innovation in practice to support public health and health improvement in the future.

In this issue, there are several articles considering health in the workplace. The pandemic has affected the way of life for communities across the world, and it has significantly impacted on the workplace for millions of people. While many are experiencing job losses, others will find new opportunities, but for the majority of those of us still working, the workplace will remain a health challenge for the future especially for those working in healthcare settings. Furthermore, increased unemployment and poverty will have their inevitable public health consequences.

Our hearts have collectively gone out to the staff in healthcare settings in the last year and Manning and Pattani describe the experiences of staff of a busy London hospital that has been seriously affected by the COVID-19 crisis. They were able to identify the psychological needs of staff working under such extreme pressures, and it was also generally acknowledged how important the local community spirit was to staff morale. In a message from the Chair of the What Works Centre for Wellbeing, Paul Litchfield reminds us all that wellbeing in the workplace should not only be reduced to the physical and mental wellbeing of employees, but greater consideration also needs to be given to the wider impact their work lives have outside of work, upon families and friends and the effect upon their employment capabilities. From Australia, Stanhope et al. call for ongoing surveillance and monitoring of the resilience of people and the work environment in relation to workers experiencing their 'effort-reward imbalance' in order to reduce the widespread impacts upon public health.

Away from COVID-19 and the workplace, we include articles on wider public health issues. In their review of qualitative studies, Rose et al., offer a unique contribution to the issue of over-prescribing of antibiotics including discussions regarding efficiency in the workplace for general physicians (GPs) and patients alike. Luo et al., report on the results from their systematic review of smoking cessation, and Kim et al. examine the quality of life for readmission patients suffering with cardiovascular disease in South Korea.

As large numbers of employees may find themselves working from home in the future, greater consideration needs to be given to the public health of individuals and families that are affected by changing circumstances at home and at work. Following this dreadful pandemic, it is inevitable that 2021 will bring permanent challenges and changes for all of us in one way or another. The Editorial Team of *Perspectives in Public Health* wish all of our readers a happy and healthy new year.

## New ‘Slow Map’ To Get The Nation Walking

During the first lockdown in 2020, with a group of 700 volunteers, geographer Daniel Raven-Ellison created a new map showing the best walking routes between all of Britain’s main towns.

For the public’s overall health and wellbeing and in an effort to keep infection and congestion down, the government’s official transport advice during the pandemic has been ‘walk, if you can’. Walking offers an exercise alternative to gyms and for those who aren’t keen on home workouts.

The new ‘slow map’ is hoped to help those leaving their local area to find the best walking routes to a nearby village, town or city.

In all, 7000 ‘slow routes’ have been identified on the map and to test them, 10,000 volunteers are needed. This will confirm whether the routes are walkable, safe and enjoyable.

Raven-Ellison said ‘If you look at the map of Britain it is covered in footpaths, but it’s a bit like a plate of spaghetti. It’s far from clear what are the best

routes if you want to walk from town to town’.

The project is backed by the Ordnance Survey, which plans to add the slow routes to its online database, following a near 1000% increase in searches for urban green spaces over lockdown.

For more information, please visit:

Slow map: Mapping Britain’s intercity footpaths. 16th October 2020. BBC News. Available online at: <https://www.bbc.co.uk/news/uk-54562137> [Last accessed 16/10/2020]

## Recreational Laughing Gas Use Linked to Risk of Paralysis



Laughing gas is the second most commonly used recreational drug in the UK for those aged 16–24. Wales’ chief medical officer Dr Frank Atherton has said that misuse of laughing gas, or nitrous oxide, can lead to permanent

damage: ‘We see people who are no longer able to walk or use their arms or legs’.

Professor Gino Martini, chief scientist at the Royal Pharmaceutical Society, and Dr Amira Guirguis of Swansea University Medical School are working together to raise awareness of these risks. They believe that overuse of nitrous oxide inhibits vitamin B12 absorption, which can lead to serious long-term effects. ‘If you get a depletion, it erodes this protective covering and it damages your spinal cord ... That’s why we see people get issues like numbness, tingling, problems with walking, and in severe cases paraplegia, which is a type of paralysis’.

Dr Atherton is concerned that young people do not have enough knowledge around the severity of nitrous oxide misuse. He adds that ‘the challenge is to get information to people to help them to understand that it is not just a harmless bit of fun. There are potentially significant consequences, particularly for people who are heavy users’.

For more information, please visit:

Laughing gas ‘can cause paralysis’, warns Wales’ top doctor 14th October 2020. BBC News. Available online at: <https://www.bbc.co.uk/news/uk-wales-54527395> [Last accessed 16/10/2020]

# Diary



*22<sup>nd</sup> February–5<sup>th</sup> March 2021, being held virtually*

## [Diploma in Occupational Medicine – Spring Course 2021](#)

This is a course approved by Faculty of Occupational Medicine (FOM) to prepare candidates for the Diploma in Occupational Medicine's written examination and the oral examination based on a portfolio. The FOM Diploma has been designed for registered practitioners. The course covers a wide range of content, including epidemiology, occupational mental health disorders, and biological monitoring.

For more information, please contact Meghan Cordery, [mcordery@rsph.org.uk](mailto:mcordery@rsph.org.uk)

*21 April 2021, being held virtually*

## [Keeping Healthcare Water Safe – 2021 Challenges](#)

This 1-day seminar, organised by the Royal Society for Public Health (RSPH), will cover topics which are still proving to be a challenge for estate managers, infection prevention and control teams, Water Safety Groups, water treatment and risk assessment providers, specialist water safety advisors, Authorising Engineers (water), and microbiologists. For more information, please visit: <https://www.rsph.org.uk/event/keeping-healthcare-water-safe---2020-challenges.html>

*27 September - 8 October 2021, method of course delivery TBC*

## [Diploma in Occupational Medicine - Autumn Course 2021](#)

This is a course approved by Faculty of Occupational Medicine (FOM) to prepare candidates for the Diploma in Occupational Medicine's written examination and the oral examination based on a portfolio. The FOM Diploma has been designed for registered practitioners. The course covers a wide range of content, including epidemiology, occupational mental health disorders, and biological monitoring.

For more information, please contact Meghan Cordery, [mcordery@rsph.org.uk](mailto:mcordery@rsph.org.uk)

# Video gaming – taking a gamble with young people’s health and wellbeing?

**Louisa Mason**

Senior Policy and Communications Executive, RSPH, London, UK

The world of video gaming has come some way from the early days of pixelated graphics and poor quality gameplay. Modern gamers have access to an inordinate choice of games, consoles, characters and in-game features. It is no wonder that the UK gaming industry was estimated to be worth £5.7 billion in 2019.<sup>1</sup>

The seemingly innocuous pastime of video gaming has various downsides that are potentially harmful for young people’s health and wellbeing. There is still debate around the reported negative consequences of increased screen time,<sup>2</sup> but a shockingly high one in two young online gamers have described being bullied when playing games.<sup>3</sup> An emerging issue that is of particular concern from a public health perspective is the increasing incidence of gambling-like features within video games, that could act as a route for normalising gambling among young people, and therefore risk engagement with harmful gambling behaviour as adults. The 2019 Royal Society for Public Health (RSPH) report *Skins in the Game* revealed that young people see gambling-like activity as a normal part of their lives,<sup>4</sup> and this is evidence of how blurred gambling and gaming have become.

Loot boxes are one gambling-like feature within video games that have gained notoriety. Loot boxes have been defined as ‘items in video games that may be bought for real-world money, but which provide players with a randomised reward of uncertain value’. They often appear as chests, crates or card packs.<sup>5</sup> There have been numerous stories of young people getting into debt, blowing through their or their parents’ savings or spending their student loan on loot boxes.<sup>6</sup> Yet under current legislation, loot boxes are not classed as a form of gambling and are therefore not subject to regulation.

The 2005 Gambling Act describes gambling as betting, gaming or participating in a lottery. The Act defines gaming as only constituting gambling, if this activity includes an ‘element of chance and an element of skill’, in an attempt to win a prize of money or something of a fixed monetary value.<sup>7</sup> As the regulator, the Gambling Commission has stated that loot boxes do not fit the current definition of gambling because winnings cannot be ‘cashed out’.<sup>8</sup> However, it is possible for players to ‘cash out’ their prizes through unregulated third-party websites,<sup>9</sup> demonstrating a loophole in the law that essentially allows children to gamble.

Children who gamble are more likely to become adults who gamble,<sup>10</sup> so we are potentially creating a generation of gamblers, and for some this could have a serious impact on health and wellbeing. Polling for *Skins in the Game* found that nearly four in five (79%) respondents said that young people could find loot boxes to be addictive, and over half (54%) of young people saw the relationship between gambling and gaming as a negative one for young people.<sup>11</sup> The COVID-19 lockdown may have exacerbated the negative impacts of gaming on health and wellbeing, with young people spending more time indoors playing video games whilst the schools were closed.

The Gambling Commission has been monitoring loot boxes amid increasing calls for them to be classed as a form of gambling. The House of Lords Select Committee on the Social and Economic Impact of the Gambling Industry released their report in July 2020, stating ‘loot boxes and any other similar games are games of chance’, and called for ‘any activity which ... has the characteristics of gambling [to] be treated as gambling’.<sup>12</sup> Similarly, the Gambling Related Harm All Party Parliamentary Group published their final report in June 2020, which specified that loot boxes should not be sold to children and require greater regulation.<sup>13</sup>

Internationally, Belgium, The Netherlands and the Isle of Man are pioneers, officiating the link between loot boxes and gambling, and taking steps to protect children and those vulnerable to harm. In Belgium, loot boxes were banned from video games;<sup>14</sup> The Netherlands ruled that some loot boxes are a form of gambling and contravene the law;<sup>15</sup> and the Isle of Man changed the law to include loot boxes, requiring games providers to acquire a licence, preventing the sale of loot boxes to under 18s.<sup>16</sup>

With increasing pressure to tackle the issue of loot boxes, and ahead of the review of the Gambling Act, the Department for Digital, Culture, Media and Sport (DCMS) launched a call for evidence on the impact of loot boxes in video games.<sup>17</sup> This consultation preceded the Government’s full response to the Online Harms White Paper and echoed the narrative of striving for the UK to be the ‘safest place to be online in the world’.<sup>18</sup>

The call for evidence focused on the experience of gamers, the impact of loot boxes, potential harms, the scale of the market and consumer protection. The primary audience invited to respond were video gamers and video games businesses, but it was expected that the industry reaction would overshadow the player’s views.

RSPH and the Gambling Health Alliance (GHA) were concerned that the voice of young people would not be heard, and thus surveyed 13- to 24-year-olds to inform our response. We believe that loot boxes should be classed as a form of gambling and regulated to ensure that underage players are not exposed to them and the potential harm they cause. The Government response is expected to largely be determined by the review of the Gambling Act; the Act has been described as 'unfit for the digital age',<sup>19</sup> and if it is to be updated to be more in line with the current state of play in the digital world, loot boxes should be included.

In conjunction with the DCMS call for evidence, the GHA launched the campaign *#LidOnLoots*. The campaign aims to continue to apply pressure to have loot boxes classed as a form of gambling and regulated accordingly to protect children. In addition, the intention is to hear from young people in greater detail about loot boxes. We want to know how loot boxes could be made safer in games played by over 18s, and what the curriculum should cover now that gambling is part of the Relationships and Sex Education and Health Education curriculum. *#LidOnLoots* will also explore whether video gamers are being scammed when purchasing loot boxes.

Please do visit [gamblinghealthalliance.org.uk](https://gamblinghealthalliance.org.uk) to find out how you can support *#LidOnLoots*, or email [gha@rsph.org.uk](mailto:gha@rsph.org.uk) if you have particular views on this issue. We are on the cusp of an influential moment in reshaping gambling legislation from a public health standpoint, to ensure that video games do not gamble with young people's future, health and wellbeing.

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The November 2020 CPD paper was 'Using e-cigarettes for smoking cessation: evaluation of a pilot project in the North West of England' by M Coffey et al.

Answers: 1a, 2a, 3d, 4b

# In Practice

## Making prevention a reality: living health and wellbeing at Sanofi



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**INTRODUCTION**

It is widely recognised that health and wellbeing is a function of many determinants, including socio-economic status, income level, education, healthcare access and societal attitudes.<sup>1</sup> One area of increasing importance, not least given the recent coronavirus pandemic, is occupational health and wellbeing.

As a global biopharmaceutical company with more than 100,000 people in 100 countries, and over 1200 in the UK, Sanofi transforms scientific innovation into healthcare solutions to

support people through their health challenges across the country, and the globe. We have a broad portfolio of treatments; we prevent illness with vaccines, provide treatments to fight pain and ease suffering, we stand by the few who suffer from rare diseases and the millions with long-term conditions. It is our mission to support people on their health journey, including that of our employees. At Sanofi, occupational health is a corporate priority due to our firm ambition to be leading in this field, but moreover is a direct consequence of our culture and commitment to being a responsible corporate citizen, prioritising health and wellbeing for the benefit of our staff as well as to help reduce healthcare costs and demand on the National Health Service (NHS).

Although the starting point for occupational health must be in the interest of public health, there are important economic and business considerations.

Evidence shows poor staff mental health and associated conditions cost employers up to £45 billion a year, with 89% presenteeism, 86% inability to switch off from work, 73% leavism and over 60% mental health absence.<sup>2</sup> Indeed, for every £1 spent on health and wellbeing initiatives, employers can achieve up to £5 return on their investment through reduced absenteeism, presenteeism and staff turnover.<sup>3</sup>

Sanofi recognises these economic imperatives and inimical impact of bad health and wellbeing on business imperatives. Sanofi’s mission is simple but critical: to protect, enable and support people.

**OUR APPROACH**

Sanofi conducted a comprehensive audit using the Public Health England toolkit to critically appraise our offering and seek best-in-class performance for occupational health.<sup>4</sup> Using a red, amber and green (RAG) rating system, this toolkit evaluates the available evidence across several areas: availability of resources, access to support, and implementation of wellbeing initiatives across physical and mental health, suicide prevention and wider health and safety. This toolkit benchmarks occupational health performance and identifies practical action plans to fill any identified gaps.

Our audit was conducted over a 3-week period and involved internal peer review focusing on feedback from internal surveys and ongoing staff needs. In addition, we undertook a

**Evidence shows poor staff mental health and associated conditions cost employers up to £45 billion a year**

benchmarking exercise in comparison to other industries/sectors to seek understanding of wider best practice. This has also been embodied in our membership of, and leadership in, the

Thames Valley Chambers of Commerce (TVCC), which has allowed Sanofi to build networks and share best practice with peers and other companies.

**OUTCOMES FROM AUDIT**

The audit showed that in terms of physical health and wellbeing, we ranked green in most domains on the RAG ratings, with some improvement areas identified. Significant investment has been made to ensure physical health is fostered using anthropologists and specialist ergonomic research to enhance working conditions. In terms of mental health and suicide prevention, our

RAG rating was largely amber with shades of green. The audit highlighted a gap in terms of amber rating of initial senior leadership buy-in, understanding and cognisance of mental health issues and their critical importance, which requires more education and training to foster a greater understanding of the pivotal role leaders must play. We further identified a lack of concrete policies and dedicated focus. This has provided a platform for focusing the organisation on prevention and building a culture of workplace health where employee wellbeing is central.

### PILLARS OF PREVENTION

Based on these critical outputs, Sanofi developed a multidimensional approach to embedding prevention, occupational health and wellbeing within the company. This includes a corporate stand-alone priority called 'Prevention', accountable to our General Manager, Hugo Fry, that sits as a critical objective across all leadership teams. Key areas are discussed below.

### MENTAL HEALTH

Our mental health offering has been significantly uplifted to include a dedicated 'Take Care and Be Well' team including mental health first-aiders, and mental health training delivered to leadership teams. We have held mindfulness sessions using qualified employees, introduced wellness cafes, and launched a mental health podcast. All employees can access an Employee Assistance Programme, which includes clinical referrals and access to counselling. Sanofi has partnered with TVCC to adopt a holistic approach to mental health and seek best practice benchmarking.

### WORKING ENVIRONMENT

Recently, Sanofi moved to a new activity-based office in Reading, specifically designed for employee health and wellbeing. This enables employees to be mindful of the activities they need to achieve and choose the best setting or location from which to accomplish them. Our internal research showed staff members were desk based for only 57% of their time and only 58% of that time was for computer-focused work. Our people are better connected through central social spaces and various technologies. The office creates an inspiring and vibrant environment, enhancing staff wellness and collaboration through its design. There are dedicated break out areas, spaces for time away from screens or devices and different styles of ergonomically designed desks to support different activities employees are working on. There are also wellness areas, spaces for exercise and a contemplation room.

During the pandemic lockdowns, we were well prepared to enable our employees to work from home immediately. As restrictions lift, our open and spacious office design accommodates a safe working environment with social distancing and one-way systems for those choosing to return to the office.

### WELLBEING CHARTER

To assess and develop health and wellbeing provision at Sanofi, a partnership with the Wellbeing Charter was agreed in June 2020. The Workplace Wellbeing Charter is an accreditation standard that is built on best practice, latest research and

business sense.<sup>5</sup> During the accreditation process, consultants assess performance against the eight pillars of the Charter. They look at current practices and policies and develop action plans to embed new practice, tackle problem areas, and test how well existing systems are working. The process begins with an interactive self-assessment tool, action plans and evidence gathering, followed by a short staff survey, and ends with a full assessment report and award of accreditation.

The review is ongoing, finishing in Q4 2020. Accreditation from the Workplace Wellbeing Charter will demonstrate Sanofi's commitment to improving the lives of those who work here.

### CONCLUSION

It was Benjamin Franklin who once said an ounce of prevention is better than a pound of cure, an aphorism that continues to ring true. This is a principle that embodies Sanofi as a business, employer, organisation, and public health partner that approaches staff health and wellbeing. Occupational health is not an optional nicety but a public health necessity, delivering significant business

**Occupational health is not an optional nicety but a public health necessity, delivering significant business benefits and savings**

benefits and savings. As part of our ongoing commitment to be a leader, our journey of prevention continues, and with it a determination to deliver the best not only to the patients we serve but

also to the staff we wish to nurture.

Sanofi Pasteur is a corporate member of the RSPH.

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# In Practice

## NHS workplace health and wellbeing during COVID-19

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### INTRODUCTION

In March, COVID-19 hit the NHS hard, in particular, London Northwest University Hospital Trust (LNWH). The global pandemic created widespread uncertainty among staff – staff were re-deployed, sent home to shield or went off sick, some for days, others months. Hourly changes were made: staff were increasingly pushed to their limits both physically and mentally, experiencing the pandemic in such varying ways.

**Staff were increasingly pushed to their limits both physically and mentally, experiencing the pandemic in such varying ways**

### BACKGROUND

As the virus rapidly spread, so did anxiety and stress levels; heightened staff support systems seemed paramount. Teams were rushed off their feet prioritising patient wellbeing; but how could we support staff during this turbulent time? Our physical presence felt most important, staff needed to be heard, they needed an outlet and we needed to understand their basic needs. We set up drop-in psychological first-aid sessions; sessions ran before, after and during shifts on or near to wards, understandably attendance levels were mixed. Emotions varied: anger, sadness and fear. Staff referred to the virus with

strong military language: ‘battle’, ‘fighting’ and ‘taking the bullets’.

It soon became apparent that staff acute needs were practical in nature; how to stay hydrated while wearing personal protective equipment (PPE), where to access hot drinks when coffee shops were shut, where could they relax during a break and what to do if they got the virus.

### SUPPORTING STAFF

Within a matter of days, our Occupational Health Department set up a COVID-19 Staff Helpline. The helpline rapidly developed from two staff taking calls to 12 staff, mostly made up of re-deployed nursing staff. No one call was the same;

callers were given advice on coming to work, shielding or isolating at home and information on up-to-date guidelines. The Trust was able to monitor staffing levels a little more easily.

With an

understanding of staff needs, a COVID-19 Staff Wellbeing Team was created. The Trust Charity played an enormous role in several of the new initiatives subsequently set up.

Staff psychological support sessions were developed by our inhouse patient psychology teams. Professionals from Macmillan and neurology specialist psychologists to mental health nurses were an integral part of this support. New pathways were set up, creating space for individuals, teams and managers to access support as and when was needed. Our employee assistance programme was used well, seeing an overall rise in usage.

KeepingWell, free wellbeing support for all healthcare staff in Northwest London, created another avenue for psychological and emotional support.

With a rise in staff isolating at home, a ‘staying at home wellbeing guide’ was created and emailed out to staff. Wellbeing posters were produced and spread across the Trust as well as motivational posters, creating a sense of strength and unity. Several staff were off work with pressures continuing to rise. The Occupational Health Department set up COVID-19 on-site and community

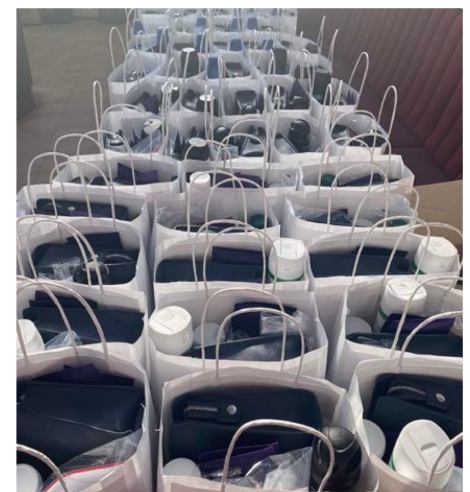
testing for both staff and their families; approximately 4000 tests have been carried out to date.

Where staff were unable to return home

to loved ones, our human resource (HR) teams worked with local hotels to create additional staff accommodation. Staff used this as a tool to continue working while protecting their families, others spent time there recovering from the Virus, no one situation was the same.

Support from the local community was incredible: donations came in thick and

**Support from the local community was incredible: donations came in thick and fast**



fast. The Trust Charity set up delivery timetables, pop-up storage, sorting and packing stations and distributed goods across the entire Trust. With few available resources, managing this huge scale of donations was exceptionally challenging.

To ensure the acute needs of staff could be met, an appeal page and a 'desired goods' shopping list was created. Businesses, individuals and communities could therefore donate required supplies, such as care pack products and tea and coffee, or make financial donations. Care packs were provided to as many staff as possible.

Monetary donations went straight into supporting staff. The Charity created staff 'pop-ups' where weekly fresh fruit deliveries were bought in, all Trust departments had access to this. Every few weeks treats were added, from Easter eggs to pastry mornings. Several coffee machines and thousands of coffee pods for the 'COVID' wards were bought – creating easy refreshment access. The 'Help Them Help Us' Charity supplied staff with free Barista made coffee for months, a hugely successful initiative.



LNWH Charity provided further coffee machines, snacks and bean bags to our Project Wingman wellbeing lounges across the Trust. Project Wingman is a fantastic initiative set up by two pilots, bringing a first-class lounge experience into the NHS. Cabin crew and pilots from across the country volunteered to run these lounges, providing staff with a wonderful environment to rest and relax in. LNWH couldn't be more grateful. Generous donations including plants, rugs, sofas and pouffes created additional welcoming spaces for staff to unwind in.

Community support continued to grow; Charities worked with our Facilities teams to provide fresh evening hot meals to staff. These wholesome meals were taken to wards and heated up at staff's convenience. Over the bank holidays, free canteen food was provided by the Trust. Bottled water was regularly sent to wards to aid with staff hydration levels.

Communication greatly impacted staff wellbeing; daily emails were sent out to staff keeping them connected with LNWH news and recent changes. A 'COVID-19 Health and Wellbeing' Intranet page was set up, creating easy access to wellbeing resources. Smaller initiatives such as Live Meditation sessions, including Gong Baths and Sound Healing, were promoted, with options to catch up on demand.

Our Occupational Health Department set up in-house antibody testing for staff, to date 74% of staff have been tested. Staff risk assessments were completed, ensuring staff health and safety was prioritised, over 92% of staff have now completed one.

## NEXT STEPS

We conducted surveys to find out what staff found beneficial and what additional support they would like, especially if a 'second wave' occurred. Additional staff psychological support was an important part of the planning. COVID-19 brought to the fore so much positivity: teamwork, staff resilience, increased community spirit and NHS appreciation, to name a few. It strengthened our community, at home and at work, with the hope of supporting one another indefinitely.

## LESSONS LEARNT

COVID-19 was completely unprecedented in its scale and longevity. To some extent, we could anticipate staff needs in the workplace; what was unexpected was the magnitude of impact it had across the whole community, affecting everyone's work and home life.

The importance of communication and teamwork stood out. Constant clear communication kept staff up to date with the ever-changing environment. New collaborations between departments provided solutions quickly and smoothly, helping to meet staff needs as and when they arose.

Addressing the biopsychosocial needs of staff was key in supporting their health and wellbeing throughout the pandemic and beyond.

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# Workplace wellbeing

*In this article, Paul Litchfield discusses the importance of wellbeing in the workplace and what that means. How does it effect our lives outside of work and what are employers doing to improve wellbeing in the workplace, and ultimately benefit their business?*

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In healthcare, we often treat the words ‘health’ and ‘wellbeing’ as being synonymous, but they are not. Wellbeing is a much broader concept which, at its simplest, can be expressed as ‘how we are doing’ as individuals, communities and society. Philosophical theories for what creates a sense of personal wellbeing date back to antiquity and broadly split into a hedonic component, whereby people seek to maximise pleasure and minimise pain, and a eudaemonic element which reflects the human need for life to have meaning.<sup>1</sup> The wellbeing of people in the workplace, therefore, needs to be viewed in terms of not only their physical and mental health but also the wider impact of their work on their lives and the effect that their social circumstances have on their employment capability.

The world of work is changing at an unprecedented pace. In what has been described as the Fourth Industrial Revolution,<sup>2</sup> new technologies are fusing the physical, digital and biological worlds and disrupting established ideas about work, the economy and even the nature of humanity. What we do, how we do it and where we do it are all changing with remarkable speed. Developed economies are now dominated by service industries

following the decline of agriculture and then manufacturing. Automation, fuelled by artificial intelligence, is replacing jobs that have formed the backbone of employment for a generation or more. For many people, ‘work’ is no longer a location but an activity and the concept of ‘a job for life’ has disappeared as people increasingly juggle multiple sources of employment with limited security of tenure. Individuals are having to adapt and so are organisations. Customers, shareholders and governments are increasingly demanding that companies behave responsibly and an important element of that is how they manage their ‘human capital’.

Promoting the wellbeing of employees is a laudable end in itself, but it is insufficient motivation for most commercial organisations to invest sustainably in a harsh economic environment. There is a growing evidence base to show that improving the wellbeing of the workforce translates into tangible business benefits.<sup>3</sup> Those benefits accrue not only in the area of cost control, such as reduced absenteeism

and presenteeism, but also extend to improved business performance. Greater employee wellbeing drives higher productivity, more innovation and better customer experience. Those are the engines for growth in any company and are critical differentiators in



a knowledge-based, service industry-dominated economy.

A growing number of companies are focusing on wellbeing in a spirit of enlightened self-interest. However, many lack a clear understanding of what they can do to shift the dial and often waste resources on uncoordinated, short-term initiatives responding to the latest fashion marketed by a burgeoning ‘wellbeing industry’. The What Works Centre for Wellbeing has developed with businesses a simple model of the key drivers of subjective wellbeing along with guidance on measurement.<sup>4</sup> The model defines four hedonic and one eudaemonic driver, which can be influenced by workplace activity:

- Health: Physical/Psychological/Emotional
- Security: Safety/Financial/Contractual
- Environment: Conditions/Culture/Systems
- Relationships: Family/Work/Community
- Purpose: Belief/Engagement/Commitment

**The wellbeing of people in the workplace... needs to be viewed in terms of not only their physical and mental health but also the wider impact of their work on their lives**

**Encouraging healthy lifestyles and improved personal resilience is worthwhile but must be supplemented by efforts to design work that is rewarding in every sense**

A key feature of successful workplace programmes is to give equal weight to activities targeted towards the individual and the organisation. Encouraging healthy lifestyles and improved personal resilience is worthwhile but must be

## Workplace wellbeing

supplemented by efforts to design work that is rewarding in every sense. The Chartered Institute of Personnel and Development has published guidance on creating and measuring 'good work'.<sup>5</sup>

Models and guidance can be helpful but most people in business are preoccupied with trying to meet escalating customer demands and can be overawed by the profusion of advice becoming available. Many companies have found that a public health approach of primary prevention, secondary intervention and tertiary rehabilitation is an effective structure for workplace implementation of wellbeing activities. Starting with a review of their existing

activities, most organisations find that they are already doing a substantial amount to promote employee wellbeing. Applying a tiered structure allows them to identify both gaps and duplication so that resources can be rebalanced, improving the affordability of enhancements. Creating a dashboard of wellbeing-related outcome measures is an essential part of implementing a sustainable system. Simple measures of personal wellbeing, such as those published by the Office for National Statistics (ONS4),<sup>6</sup> should be supplemented by business-related measures that capture both the cost of poor wellbeing and the benefits of good wellbeing.

Adopting a wellbeing approach within an organisation can be transformational. Looking at the people agenda through a wellbeing lens alters the perspective on many policies and procedures. The synergies (and sometimes conflicts) between isolated activities in reward, recruitment, organisational design, learning and talent, as well as health and safety, become apparent and can be aligned so that the whole is greater than the sum of its parts. Organisations that embrace the concept and execute it effectively will not only have happier, healthier workers but also are likely to survive and prosper through the turbulent years ahead.

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# Organisational injustice from the COVID-19 pandemic: a hidden burden of disease

*During the current climate, the workers' experience is constantly changing, with increased workload and a reduction in promotion and bonus opportunities. This leads to an increase in effort-reward imbalance (ERI) experienced by workers. In this article, Stanhope and Weinstein, outline the health effects of this and how businesses can strategise to reduce it.*

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The health focus of 2020 has certainly been the direct and indirect effects of coronavirus disease 2019 (COVID-19). The immediate threat in most countries has been the direct effect, and as our understanding of COVID-19 grows, the potential long-term impacts of the disease are becoming increasingly apparent.<sup>1-4</sup> Many of the indirect effects of COVID-19 relate to the lockdowns imposed in most countries, such as loss of income and social contact, and limited access to healthcare. These are important, complex and enduring health issues that require significant attention. Undoubtedly, there are additional, hidden, health outcomes that are bound to emerge with time and research, and one such issue that we anticipate is the indirect disease burden of COVID-19-

related organisational injustice, for those who have *remained* at work.

People who have remained working are in many respects very fortunate. The economic fallout from COVID-19 has been extensive, leading to significant job losses internationally, but this is not to say that those who have remained in work (and avoided contracting COVID-19) are free

**The significant job losses across many industries have meant that remaining staff often do more work to make up the shortfall**

from the indirect health impacts of COVID-19. For many workers, their actual or perceived effort required at work has increased due to COVID-19: the significant job losses across many industries have meant that remaining staff often do more work to make up the shortfall, and/or are taking on higher duties and responsibilities due to superiors losing their jobs. For some people, working from home has also brought with it increased real or perceived effort, particularly when balancing childcare/home-schooling duties. At the same time, rewards for work have typically decreased. Such rewards include esteem, pay, promotion opportunities and



**Job security has decreased for many during COVID-19, pay is being cut, workers are being forced to take leave, and may have reduced promotion opportunities because of employer financial stress and instability**

job security. Job security has decreased for many during COVID-19, pay is being cut, workers are being forced to take leave, and may have reduced promotion opportunities because of employer financial stress and instability. The chances of workers experiencing

effort-reward imbalance (ERI) – a form of organisational injustice – during COVID-19 are therefore likely increased.

ERI occurs when perceived efforts exceed perceived rewards.<sup>5</sup> This situation is maintained when individuals are overcommitted to their work, are being strategic, and/or do not feel they have alternative work opportunities.<sup>5</sup> ERI is likely to continue for many workers, so long as the effects of the pandemic are being felt and solutions like alternative employment opportunities remain limited. When ERI occurs, the stress axes in the brain are activated, including the hypothalamic–pituitary–adrenal axis; the result is a cascade of events that may ultimately cause or exacerbate a range of stress-related diseases.<sup>5</sup> These diseases include

## Organisational injustice from the COVID-19 pandemic: a hidden burden of disease

depression,<sup>6</sup> cardiovascular diseases,<sup>7</sup> diabetes<sup>8</sup>, and musculoskeletal disorders,<sup>9</sup> which are some of the leading causes of morbidity<sup>10</sup> and mortality<sup>11</sup> globally. Thus, both ERI at work, and the disease burden resulting therefrom, are likely to increase as a result of the COVID-19 pandemic, contributing to the already high burden of non-work-related stress as a public health problem at the population level. We are on the path to a post-COVID-19 public health crisis, and it is likely that ERI at work will contribute thereto.

To reduce the indirect impact of COVID-19-related ERI on workers' health, several strategies may be employed. While significant changes are likely to be required for businesses to stay viable, the impact of such changes on employees may be reduced by working *with* employees directly to establish the most acceptable solutions.

To further address ERI, strategies may focus on addressing individual elements of effort and/or reward. For instance, there may be inexpensive strategies to improve reward, such as deliberately communicating the value of the staff to the

organisation (addressing esteem), or reducing effort by discussing which elements of the job may not be required or could be minimised (e.g. some meetings). Another strategy may be

**There may be inexpensive strategies to improve reward, such as deliberately communicating the value of the staff to the organisation (addressing esteem)**

working with individuals to provide them with opportunities to influence the selection of any tasks they are required to perform. This approach could allow staff to select tasks they find easy or enjoyable (and therefore of little additional perceived effort), and/or tasks that may be strategic, thus improving future work opportunities. If administered effectively, these strategies would likely reduce the negative health impacts of ERI at work because of COVID-19.

Obviously, in some instances, it might not be possible to adequately address ERI during the COVID-19 pandemic and in the years that follow. Additional approaches are therefore required to counteract the negative impact of COVID-19 on work health and safety.

Such approaches may include addressing other risk factors for adverse health outcomes for workers, including

both physical and psychosocial factors. Consistent with this approach, workers need opportunities to openly discuss their work challenges, without being dismissed as just lucky to remain in employment. In fact, some workers may

require additional encouragement to discuss their work challenges, as they themselves may be more reluctant to open up as a result of their own awareness of being fortunate to remain in

employment. Employers can encourage supportive communication by providing and encouraging free counselling sessions for their staff – a service that could also be perceived as a reward. Supporting workers during COVID-19 is important, despite their relatively fortunate position.

ERI and other forms of organisational injustice are common, but are likely exacerbated by the COVID-19 pandemic. The financial impact of COVID-19 will extend long beyond the pandemic itself, and ERI is therefore likely to continue to exacerbate disease burden for some time to come. The indirect health implications of COVID-19 on workers should therefore be monitored, and the impact of interventions to address ERI studied. The findings of such studies will be invaluable to inform work practices following any disaster situation, including recession, natural disasters, terrorism, wars and future pandemics. Ongoing monitoring/surveillance and adaptive management are key to any serious attempt at long-term recovery and resilience of both people and environment following any disaster.<sup>12</sup> By learning from the health effects of ERI during the COVID-19 pandemic, we will be better placed to prepare for and respond to disasters generally, thereby reducing their indirect, but widespread, impacts on public health.

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# Achieving integrated care: the need for digital empowerment

*In this article, Knight and Burdett look at the complex challenges involved in integrating care systems as part of the NHS Long-Term Plan of 2019, and the importance of digitalising services and records for implementing this.*



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'Integration' is at the centre of the NHS Long-Term Plan of 2019,<sup>1</sup> with a continuing emphasis on place-based systems and integrated care. This has been a fundamental aspect of recent NHS policy, with a strategy to 'use the next several years to make the biggest national move to integrated care of any major western country'.<sup>2</sup> Building on these fundamentals, the 2019 Plan promises the development of totally integrated community-based healthcare. It spells out a strategy for all areas of England to be part of

integrated care systems (ICS), which by April 2021 will normally be one clinical commissioning group (CCG) per ICS area. New integrated systems of care are anticipated to enhance population health by improving service provision outside hospitals, with prevention and personalised care<sup>1</sup> being central components of the Plan.

Integrated care can bring an extensive scope of benefits.<sup>3–6</sup>

The intrinsic basis is that 'integrated care is adaptable and can respond to the local arena whether that is due to our patient population health and care needs, resource issues or evolving societal changes'.<sup>3</sup>

Personalised care is, by its own definition, holistic. It needs to be available in the format of joined-up services for patients, which need to be fortified by a multidisciplinary partnership approach, with networks stretching across and through health, social care and the voluntary sector. The planned integration of primary and secondary care, which includes social care and the voluntary

**New integrated systems of care are anticipated to enhance population health by improving service provision outside hospitals**

agencies, is underpinned by £4.5 billion of new investment. This is anticipated to create expanded community multidisciplinary teams within the integrated care systems.<sup>1</sup> A strategic emphasis on integration will require 'streamlined commissioning arrangements'<sup>1</sup> where

neighbouring general practices will join together to form primary care networks (PCNs), which will usually include 30 – 50,000 people.

However, there are several challenges to integrated care. In particular, these relate to digital technologies and digital literacy, both of health and social care professionals and also the population,

which may impede these changes.<sup>3,7</sup> The digitalisation of health provision underpins many of the changes envisaged for the NHS and is depicted as central to the enhancement of patient care and NHS reform.<sup>1</sup>

System change and investment is required to enable such an

ambitious use of technology. The National Programme for IT (NPFIT), a £10 billion-plus investment in digitising the records of all NHS patients, 'only achieved a fraction of the original vision'.<sup>8</sup> The present investment, infrastructure and digital volume within the NHS, and the expertise necessary to enable successful future projects to materialise, may well be crucial obstacles to effective digitalisation of services and provision.<sup>9</sup>

The workforce itself requires training and upskilling to cope and be confident with new technologies. In addition, they need to be flexible and adaptable given the fast pace of change, as new systems are constantly being developed and implemented. The onus for this upskilling is not only on the individual, but is also incumbent on employing organisations and educational establishments alike to facilitate and support this. Furthermore, some segments of society, including older people, may feel disregarded or have communication difficulties that make digital access less suitable for them.<sup>9</sup> Fenge et al.<sup>10</sup> identified that older users of technology are not one homogeneous

**The digitalisation of health provision underpins many of the changes envisaged for the NHS and is depicted as central to the enhancement of patient care and NHS reform**

group as there are vast differences in ages, skills and morbidities/co-morbidities. This means that 'usability, learnability and efficiency and satisfaction for the user'<sup>11</sup> need to be considered when empowering older people to develop their digital literacy skills. Issues of equity and access to

health and social care between urban and rural areas, as well as the differences within the broadband infrastructure, need to be addressed.<sup>11,12</sup>

Ultimately, these complex challenges need to be addressed by digital empowerment if the roll-out of digital

health proposed within the NHS Plan is to be successful.

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RESEARCH

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# Family doctors' roles and perceptions on antibiotic consumption and antibiotic resistance in Romania: a qualitative study

Ioana Ghiga<sup>1\*</sup>, Emma Pitchforth<sup>2</sup>, Cecilia Stålsby Lundborg<sup>1</sup> and Anna Machowska<sup>1</sup>

## Abstract

**Background** Antimicrobial resistance (AMR) is a major global health issue, bringing significant health burden and costs to societies. Increased antibiotic consumption (ABC) is linked to AMR emergence. Some of the known drivers of ABC are antibiotics over-prescription by physicians and their misuse by patients. Family doctors are recognised as important stakeholders in the control of ABC as they prescribe antibiotics and are considered a reliable source of medical information by patients. Therefore, it is important to explore their perceptions, especially in Romania, which has the highest ABC among European Union Member States. Furthermore, there is no published research exploring Romanian family doctors' perceptions regarding this phenomenon.

**Methods** This was a qualitative study with data collection via semi-structured interviews among 12 family doctors. Manifest and latent content analysis was used to gain an in-depth understanding of their perceptions. Findings were mapped onto the domains of the Behaviour Change Wheel to facilitate a theory driven systematization and analysis.

**Results** Two main subthemes emerged: i) factors affecting ABC and prescribing and ii) potential interventions to tackle ABC and antibiotic resistance. The factors were further grouped in those that related to the perceived behaviour of family doctors or patients as well as those that had to do with the various systems, local contexts and the COVID-19 pandemic. An overarching theme: 'family doctors in Romania see their role differently when it comes to antibiotic resistance and perceive the lack of patient education or awareness as one of the major drivers of ABC' was articulated. The main findings suggested that the perceived factors span across the capability, opportunity and motivational domains of the behaviour change wheel and could be addressed through a variety of interventions – some identified by the participants. Findings can also be viewed through cultural lenses which shed further light on the family doctor- patient dynamic when it comes to antibiotics use.

**Conclusion** Potential interventions to tackle identified factors emerged, revolving mostly on efforts to educate patients or the public. This exploratory research provides key perspectives and facilitates further research on potential interventions to successfully address AMR in Romania or similar settings.

**Keywords** Antibiotic resistance, Antimicrobial resistance, General practitioners, Family doctors, Perceptions, Roles, Romania

## Background

Antimicrobial resistance (AMR) is a major issue globally, bringing significant health burden and high costs to societies. In the European Union (EU), AMR is estimated to lead to 33,000 deaths per year and €1.5 billion yearly losses due to healthcare and productivity costs [1]. While several

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policy instruments were developed to control this phenomenon [2–4] data across EU Member States, show wide variation in antibiotic consumption and resistance rates [5–7].

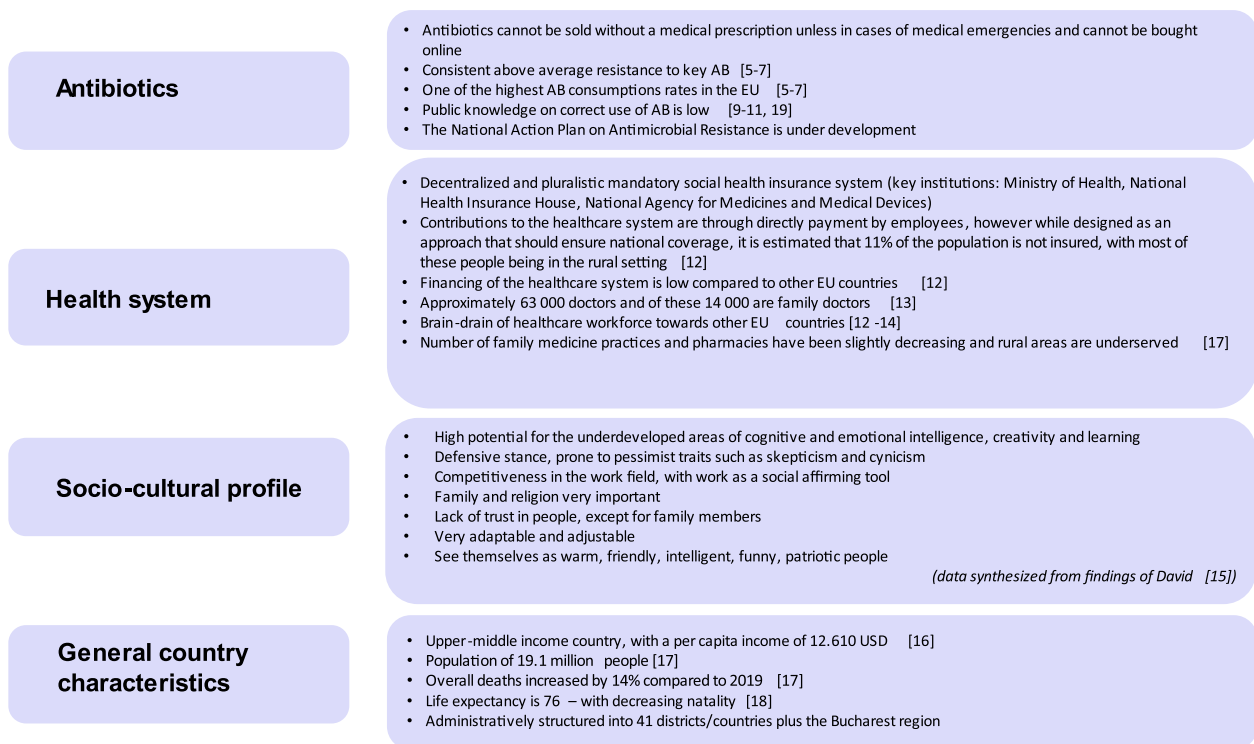
Romania, who joined the EU in 2007, is among the top most affected countries with over 3% of its population using antibiotics daily [8]. Based on latest data from 2021, Romania ranks first among all EU members states when it comes to consumption of antibacterials for systemic use in community and hospital sector [7].

Figure 1 presents key details on the Romanian context [5–7, 9–19], references are also listed in the figure content).

This data suggests the need to curb antibiotics consumption including at the community level in Romania. This can be achieved by addressing related drivers, which result from antibiotics over-prescription by physicians, their dispensing without a prescription by pharmacists and their misuse by patients. These drivers are linked to knowledge, attitudes and practices of key stakeholders and would necessitate a greater understanding of factors that may predict, alter and promote responsible behaviours when it comes to antibiotic use [20]. In Romania there is very little research in this area. A previous study looked at the community pharmacists' perceptions on their role in respect to AMR [21] and highlighted the perceived health system barriers that patients face in accessing care, the different

negative incentives that determine pharmacist to push the limits of the law, the areas of improvement such as a more collaborative approach, the need to invest more in educational interventions for both pharmacists and the general public. These findings resonate with other results, which highlighted high prevalence of self-medication practices in the Romanian context [19]. While a study from 2019 conducted in one Romanian county -Mures, found that the majority of participants had good knowledge of antibiotic usage and the risks of self-medicating with antibiotics [22], recent Eurobarometer results seem to be less encouraging [9]. Among all EU countries, Romanian respondents had the lowest average number of correct answers with a decrease in knowledge compared to results from previous years [9]. Findings from the same survey show that doctors are considered as the main source to obtain information on antibiotics followed by pharmacists [9].

Previous systematic reviews [23–25] revealed several drivers that may influence GPs or family doctor's decision to over-prescribe antibiotics. These can be structured as: i) physician-related factors such as complacency driven by a desire to maintain patient satisfaction and avoiding conflict, anxiety and fear, ii) patient-related factors which ranged from symptoms and co-morbidities, predisposition to complications that, based on the physician's experience, demanded antibiotic treatment, pressure and a



**Fig. 1** Key data on Romania

lack of patient education and awareness; and iii) health-care system-related factors that placed pressure on time doctors could allocate to patient consultation, lack of policies and guidelines as well as lack of access to facilities (for either testing or treatment). In Romania, to our knowledge, there is no published research identifying the views of GPs and family doctors on the drivers that may influence their behaviour regarding antibiotic prescription or the antibiotic consumption and resistance problems in general.

Against this background we undertook a qualitative research study, with the aim to increase the understanding of how family doctors perceive the phenomenon of antibiotic consumption and antibiotic resistance in Romania, including how they see their roles in this respect. This research is particularly timely, within the context of the development of the Romanian National Action Plan to tackle AMR. More widely presented results would also increase the knowledge base for countries that share similarities with Romania and are in the course of developing their national action plans.

## Methods

### Study design

This exploratory study used qualitative research methodology and content analysis to gain an in-depth understanding of the views and experiences of family doctors in Romania. The use of qualitative methodology was considered optimal as antibiotic misuse and over-prescribing practices are complex phenomenon. Their drivers are rooted in behavioural concepts, that merit a deeper understanding of the different stakeholders' experiences and perceptions. Moreover, considering the limited research in the Romanian setting, qualitative methods allow to appropriately engage in these initial explorations.

### Data collection tools development and validation

The interview guide (see Annex 1) was developed by identifying key concepts through literature review as well as was guided by the overall research questions. Therefore, the questions aimed to gather contextual information such as opinions on the problem of unnecessary antibiotic consumption and antibiotic resistance in Romania and the role of family doctors in this area, drivers that would determine unnecessary requests and/or prescribing of antibiotics, potential interventions to curb antibiotic use and related considerations for their operationalisation and impact monitoring. The interview guide was developed in English and then translated in Romanian. It was tested on the first participant. The questions that were aimed to understand the resource needs and potential impact did not yield many reflections from the participant. This was also noticed in subsequent

interviews and were deprioritised when interviewees expressed time-constraints for the interview.

### Recruitment

The recruitment strategy was guided by the aim to achieve maximum variation in terms of professional experience, geographical and gender distribution as well as variation in terms of urban/ rural place of work. This was envisaged to allow emergence of comprehensive themes. Different recruitment strategies were used to achieve this. A first strategy to reach relevant informants was to contact the National College of Physicians in Romania, who posted the invitation to participate in this research on their website. Secondly, purposive sampling was sought to achieve geographical and gender variation, by directly contacting doctors by phone through the publicly available contact data posted on the Romanian national insurance registry. Social media (Linked In platform) was also used to disseminate information on this research. In total approximately 200 family doctors were directly contacted over the phone to participate in this research between late August and end of October 2021. Of these 12 participated, the rest declining. All but one interview was performed by telephone (one was conducted face-to-face). The most common reason given for non-participation was the lack of time, some mentioning this is also due to heavier workload due to COVID-19, and in some cases a self-assessed lack of suitability, considering that an infectious disease specialist would be better suited to engage in an AMR research project. While doctors were contacted from all geographical regions, with similar efforts (telephoning at least five doctors in a certain county), no participation was attained from doctors from the East and South-East region of Romania. All potential participants were provided with study information ahead of giving informed consent to participate.

### Data collection

Interviews were conducted in September and October 2021, with one exception for an interview conducted in October 2020 (which was also used to test the interview guide). The interviews were conducted by the first author (IG) in Romanian language, and were audio recorded. The interviewer was native Romanian speaker. They lasted between 15 and 90 min, with an average of 30 min. Interviews were conducted within one- or two-days following confirmation of availability. Saturation was reached following 11<sup>th</sup> interview, and one more interview was carried out to confirm this assessment. By saturation, we understand that interviews no longer involved provision of new information, and interviews were making smaller contributions compared to the previous ones.

Participation was voluntary with no remuneration being offered.

**Data management and analysis**

The audio records of the interviews were transcribed verbatim in Romanian. These were then translated into English. Content analysis was used to identify manifest categories and latent themes. Content analysis was used over thematic analysis, as there was an assumption that the data will allow description but may offer different levels of interpretation. Thematic analysis requires a more abstract level of abstraction and interpretation, which given the exploratory, reduced size of research may have raised issues around accuracy of interpretation of hidden meaning and potential loss of valuable information [26]. Excel was used to facilitate data analysis. Coding was employed to compile consistent and exclusive categories which reflected the manifest level. First, meaning units were identified and condensed. The condensed meaning units were grouped into sub-categories and lastly categories. Subsequently, these lead to sub-themes which were analysed to infer the underlying meaning. An attempt was made to articulate an overarching theme reflecting the latent meaning and overall interpretation of data. Findings were also mapped onto the domains of the Behaviour Change Wheel [27] which lists the domains of the Capability, Opportunity and Motivation Model of Behaviour (COM-B) as well as intervention functions and policy categories as shown in Fig. 2. This framework aims to foster an understanding of the behaviour that is

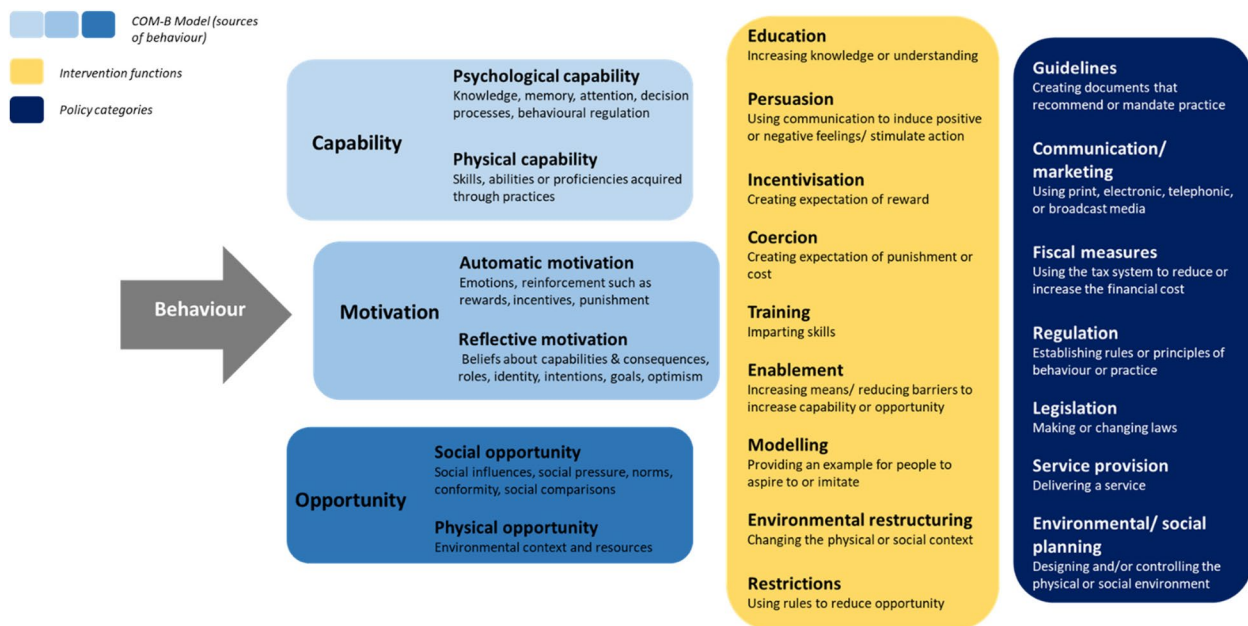
meant to be modified, as well as offer a system to characterize a range of interventions, including policies, by linking them to specific behaviour components such as the capabilities, opportunities and motivations that form the behaviour. The COM-B has been used to aide evaluations of community-based interventions to tackle AMR as part of two systematic reviews [28, 29]. Therefore, we consider it opportune to align to these efforts and enable future comparable analysis to aid further research on the design, implementation and evaluation of behavioural change interventions. The analysis was led by one researcher. The analysis was discussed with the broader research team to interrogate findings and interpretation.

**Ethical considerations**

The research was reviewed and approved by the National Bioethics Committee of Medicine and Medical Devices in Romania – approval registration no 3SNI on 17.02.2020. Participants were informed about the nature of the research, their right to refuse or stop participation at any moment. All participants received and signed the corresponding informed consent form.

**Results**

In total the research findings draw on responses of 12 participants with ages between 35 and 71, of which 42% were female. Only one participant worked in the rural setting. Family doctors worked in direct contractual agreement with the National Insurance House in Romania and did not work through private clinics.



**Fig. 2** Adaptation of the Behaviour Change Wheel [27]. COM-B, Capability, Opportunity and Motivation Model of Behaviour

Two main subthemes emerged following data analysis. These were: i) factors affecting antibiotic consumption and prescribing and ii) potential interventions to tackle antibiotic consumption and antibiotic resistance. An overarching theme was also articulated: family doctors in Romania see their role differently amongst themselves when it comes to antibiotic resistance and see lack of patient education or awareness as one of the major drivers of antibiotic consumption.

The results of the content analysis are presented in Table 1. We then map identified factors and interventions to tackle antibiotic consumption and resistance as expressed by family doctors in Romania on the Behaviour Change Wheel [27]. Considerations are explored in the discussion section.

**Factors affecting AB consumption and prescribing**  
 • *Family doctors related factors*

**Different understanding of the magnitude and causes of antibiotic consumption, resistance and prescribing**

Participants offered different perceptions on the extent of the antibiotic consumption and AMR in Romania. While

some were aware of the current official statistics, some mentioned the situation improved drastically as the result of changing of legislation, which limited pharmacy sales without prescription, and this is no longer an issue. Another participant mentioned that one cannot notice necessarily the extent of the problem from direct medical practice.

*INT2 (female, 35 years old): We are in second place in Europe when it comes to antibiotic resistance. This is a very worrying situation.*

*INT4 (male, 50 years old): I don't think this [AMR] is a problem. It used to be a problem in the 90 s when antibiotics were dispensed without prescription.*

There were also varying opinions about the family doctors' role and contribution to the phenomenon with some considering there is over prescribing from the family doctors and paediatricians, that the family doctors have a small influence or that other specialities would be better placed to engage when it comes to AMR. Furthermore, the problem was perceived by some participants as being more prevalent and serious due to the hospital setting where drug-resistant bacteria emerge, and is less of a community driven phenomenon.

**Table 1** Overview of manifest and latent meaning findings

Manifest meaning (categories in bold and subcategories plain text)	Subthemes	Latent meaning Overarching theme
<p><b>Family doctors related factors</b></p> <ul style="list-style-type: none"> <li>• Different understanding of the magnitude and causes of antibiotic consumption, resistance and prescribing</li> <li>• Interpretability of existing guidelines, lack of diagnostics, reliance on experience and complacency</li> </ul> <p><b>Patient related factors</b></p> <ul style="list-style-type: none"> <li>• Undue pressure and transfer to another doctor</li> <li>• Poor medical knowledge</li> <li>• Opportunities to acquire antibiotics from other sources</li> <li>• Lack of treatment adherence</li> </ul> <p><b>System and contextual factors</b></p> <p><b>COVID-19 pandemic exacerbated antibiotic consumption and hinders other public health campaigns</b></p> <p><b>Local communities provide better opportunities for greater engagement with the general public</b></p>	<p>Factors affecting antibiotic consumption and prescribing</p>	<p>Family doctors in Romania see their role differently when it comes to antibiotic resistance and see lack of patient education or awareness as one of the major drivers of antibiotic consumption</p>
<p><b>Enhancing medical knowledge for health-care professionals</b></p> <p><b>Statistics and feedback loops to be used with caution</b></p> <p><b>Public education</b></p> <p><b>Controls in pharmacies</b></p> <p><b>Antibiotics packaging</b></p>	<p>Potential interventions to tackle antibiotic consumption and antibiotic resistance</p>	

*INT2 (female, 35 years old): There is an abuse of prescribing antibiotics, it's enormous .. and the paediatricians.. I think in first place are the family doctors and the paediatricians. and the rest of specialities follow.*

*INT5 (male, 53 years old): Oh dear, but you are asking a family doctor, you should be asking a specialist, me as a family doctor what can I tell you.. I don't know what to tell you.. I am not working with antibiotics .. more like this, from my medical knowledge. This is a topic for an infectiousness.*

#### **Interpretability of existing guidelines, lack of diagnostics, reliance on experience and complacency**

Existing guidelines were considered useful. It was stressed that their role is to guide the doctor, which ultimately needs to decide whether it is appropriate to follow provisions. The fact that guidelines are open to interpretation, meaning that the provisions are broad and not mandatory, brings strengths and weaknesses. It was mentioned that it may be beneficial to have more direction on which antibiotics should be used first. Furthermore, better diagnostics capacities would also help doctors.

*INT12 (male, 61 years old): The guideline remains a matrix, which you can use or not, that's why it's a guide. But the treatment must be individualised, and here is where the experience of that doctor is important.*

One participant also mentioned a situation where family doctors may give out antibiotics, not because of lack of knowledge but rather out of complacency.

*INT9 (male, 47 years old): There are situations where family doctors give out antibiotics not because they don't know but because of complacency.*

#### **• Patient related factors**

#### **Undue pressure and transfer to another doctor**

Family doctors perceived that patients could exert pressure by asking for antibiotics and eluding to moving to another doctor in case of dissatisfaction. However, by building rapport and by strengthening patient-doctor communication, it was considered that patients would ultimately understand they would be prescribed antibiotics only when needed.

*INT6 (male, 56 years old): The influence of family doctors is very small, because me for example as a*

*family doctor I am against abusive use of antibiotics, but the patient will just go to another doctor.*

#### **Poor medical knowledge**

Patients' knowledge on use of antibiotics and risks associated with misuse was considered to be insufficient and considered a major source of antibiotic consumption. This may also have been perpetuated by past obsolete medical practices. Participants were also asked whether the social-economic situation of a patient may influence their decision to take antibiotics, but this was not seen as a major factor compared to the educational component.

*INT2 (female, 35 years old): A lot of medical education, two folds – once with the doctors, a re-evaluation of the indications and ways of prescribing, and secondly patients' education, because many times, these antibiotics are prescribed at the request of the patient. There is a certain type of pressure for which you need to be very prepared for. Patients in Romania, the big mass of people, they live with the conviction that the antibiotic is antipyretic, analgetic .. when you tell them there is no reason why you should be taking antibiotics when you have a cold, the answer is 'Yes, but I have a fever' or 'I have a headache'*

#### **Opportunities to acquire antibiotics from other sources**

The lack of knowledge and assumption that antibiotics should be taken for any cold-like symptoms, is also credited to be the cause of patients starting the treatment at their own volition by obtaining antibiotics either from pharmacies or from the emergency setting.

*INT7 (male, 71 years old): [...] they say for them it only passes with antibiotics and they insist, I am not a proponent of antibiotics but [...] still in our country, in a pharmacy, if the person insists, they are dispensed an antibiotic without a medical prescription even if now it's more regulated, they still can get it, if not, they borrow from their neighbours ..*

Furthermore, patients are also thought to take antibiotics from acquaintances that may not have any medical training. Patients would then need to return the 'borrowed' antibiotics.

*INT3 (female, 60 years old): The law should be respected – they come though having already started the treatment: 'I already started taking Augmentin, could you please give me some to continue and I also*

want to return some to my neighbour' [...] There are situations where people want to have an antibiotic at home, or to have a spare if they go abroad.

### Lack of treatment adherence

Obtaining antibiotics, even if in small quantities, from other sources leads patients to arrive at the family doctor once they finish these 'emergency' doses. In such situations the doctor reported feeling forced to prescribe antibiotics so that they can have a minimum number of days to continue treatment. While less frequent, lack of adherence to following through the treatment was also mentioned, with some patients arbitrarily deciding to stop taking antibiotics as soon as symptoms improved and save the pills for other occasions.

*INT7 (male, 71 years old): Yes, they come and they say they took amoxicillin .. and then so that you are not in the situation to create a sensitization to that antibiotic, you need to continue at least 2-3 days, if they took it, at least to have the full treatment;*

#### • System and contextual factors

Participants reflected that broader system and contextual factors were relevant, for example the pharmacies were perceived to be dispensing antibiotics without prescriptions in high numbers therefore contributing to misuse of antibiotics.

*INT1 (female, 62 years old):.. I noticed that in the big pharmacy chains they no longer give out antibiotics, but in the small ones they still do, and they no longer come to the family doctor and they say that the 'pharmacy doctor' gave them the antibiotics.*

Another factor that may impact decision to prescribe antibiotics was the patients' living situation, suggesting that a patient located in a rural setting may have difficulties in accessing medical care and return to 'control visits', therefore it may be more prudent to prescribe antibiotics.

*INT10 (male, 53 years old): it's one thing to treat someone in town, 300m from the practice and it's something different to treat someone who lives 20 km in the woods somewhere. That's why I'm saying that treatment individualisation needs to be very well thought through.*

### COVID-19 pandemic exacerbated antibiotic consumption and hinders other public health campaigns

The COVID-19 pandemic is thought to have exacerbated antibiotic prescribing and consumption due to the early recommendation of prescribing azithromycin for COVID-19 patients. Most of participants expressed

a lack of understanding why this was recommended by the Romanian authorities. Furthermore, at the time of the interviews, participants also considered that due to the unfolding pandemic, no other public health- oriented campaign (such as one to educate the public) would be feasible or efficient due to the ongoing vaccination campaigns.

*INT2 (female, 35 years old): There needs to be an educational campaign, but now it's not possible as another campaign should be taking place...I never understood though why we were asked to prescribe azithromycin for COVID-19.. honestly, nobody explained.*

It was also expressed that while hygiene efforts intensified and this may have a positive effect to reduce bacterial infections, not much can be learned from the current COVID-19 behaviour change interventions, as these were not seen to be effective (e.g. encouraging vaccination).

*INT5 (male, 53 years old): I think it's an inefficient campaign [about the COVID-19 vaccine], without much planning.. mostly it's disinformation.*

### Local communities provide better opportunities for greater engagement

It was stressed that local communities provide better opportunities to engage and tailor approaches for better uptake.

*INT12 (male, 61 years old): I don't think this is necessarily a system thing more about local actions [...] local initiatives are very good because they account for specificities and someone that actually works locally, is invested personally and is known, they should be involved to see this through.*

### Potential interventions to tackle antibiotic consumption and AMR

#### Enhancing medical knowledge for healthcare professionals

Activities such as round tables and symposiums have been mentioned as interventions that would aid with improving or refreshing medical knowledge on antibiotics. These events should occur periodically, have a multi-disciplinary composition, although most of the time only doctors of different specialities were mentioned as potential participants. Preferably these events should not take place in an online format (which was found to have low participation and engagement).

*INT3 (female, 60 years old): More round-tables discussions should be organized. And periodically, not only once. Infectious disease specialists, Ministry of Health representatives, pharmacists and dentists should be invited.*

### Statistics and feedback loops to be used with caution

While it may be useful to have access to statistics which could be supplied through periodic newsletters, when it comes to prescription data it is important not to judge numbers disjointly from the medical cases history as antibiotic prescriptions could have been necessary. Participants expressed worries that an approach to limit antibiotic prescribing, as employed in other western European countries may not be suitable, as they have had patients returning to Romania with very serious infections for which they received paracetamol.

*INT12 (male, 61 years old): A simple monthly doctors' prescriptions report won't say whether the antibiotics were necessary or not, it won't express seriousness.*

*INT10 (male, 53 years old): We know there are countries like Sweden, the Nordic countries, England which are more severe, but also from there, I had patients coming with sinusitis that were poorly managed, with a perforated timpan because of the reticence to keep things under control with an antibiotic – this isn't a good approach either; the approach should be to individualise the treatment.*

### Public education

Educating the public has overwhelmingly been suggested by all participants as a potential intervention to tackle AMC and AMR. Suggested channels to conduct educational campaigns vary from family doctors' practice, pharmacies, schools, social media and most importantly through TV. However, participants stressed that impact would not be noticeable in the short timeframe.

*INT10 (male, 53 years old): Doctors need to be trained through materials, be notified about new medications, a lot of population education ..but this is a continuous effort, that will take years and maybe then a generation will appear which will take less antibiotics.*

Children have been mentioned as a good target group, especially secondary and high-school students so that good behaviours could be inculcated early. However, challenges would consist of the reduction in numbers or the lack of school doctors. Games and cartoons could be used to convey medical messages in a friendlier format.

*INT2 (female, 35 years old): It would be wonderful, that this effort starts with young ages. Children of course, don't have the power of deciding, but it does prepare them for the future. Secondary school would be best.*

However, as efforts to educate the public and health-care professionals increase, there needs to be special attention to the growing trend of distrust in science.

*INT12 (male, 61 years old): I think there is a challenge with the entire perception on science... Trust in science, less dogma.*

### Controls in pharmacies

Greater controls in community pharmacies was suggested due to suspicions that antibiotics are dispensed without prescription in cases that may not be emergencies (which is the current law).

*INT11 (male, 59 years old): there is a complicity from the part of pharmacies [...] it has changed only partially because we still are living with this tendency from the pharmacist to compete with the doctor's profession, this is my opinion.*

### Antibiotics packaging

One participant drew a parallel with tobacco and alcohol labels and mentioned that learning from this field could be applied to warn patients on the dangers of antibiotics misuse.

*INT7 (male, 71 years old): well for children we could do some cartoons related to antibiotics, and similarly for adults, just like we do for cigarettes packaging, for alcohol, circulation accidents.*

### Discussion

This was the first study aimed to offer a greater understanding of the family doctor's views on the factors that may affect antibiotic consumption and emergence of resistance as well as explore potential interventions that could be implemented in the Romanian setting. Our findings suggest that the perceived factors span across the capability, opportunity and motivational domains of the behaviour change wheel and could be addressed through a variety of interventions. A synthesis of the factors and of the related, identified and potential additional interventions are presented in Table 2. The identified driving factors are overall consistent with findings from other settings as presented in several systematic reviews [23–25].

Regarding needed capabilities, family doctors' in Romania identified difficulties linked to lack of diagnostics capacities. This is consistent with other research that called for a need to have rapid tests that would enable diagnostics at point of care and would complement empirical prescribing practices [30]. Factors that refer to psychological capabilities relate to the different



**Table 2** Proposed intervention functions and policy categories for the identified factors

COM-B Model Domains	Identified factors	Intervention functions	Policy categories and interventions identified by participants	Detailed interventions including examples of additional potential interventions or policies from other settings
<b>Physical capability</b>	Lack of diagnostics	Incentivisation		<ul style="list-style-type: none"> <li>Enhanced access to antibiograms</li> <li>Availability of rapid diagnostic tests</li> <li>Enhancing physical capability for parents to perform rhinopharyngeal clearance</li> </ul>
<b>Psychological capability</b>	Different understanding of ABC and AMR magnitude	Enablement	<ul style="list-style-type: none"> <li>Periodic updates with statistics</li> </ul>	<ul style="list-style-type: none"> <li>Enhanced surveillance networks</li> <li>Auditing and feedback mechanisms on GP prescriptions</li> <li>Newsletters with:                             <ul style="list-style-type: none"> <li>Statistics</li> <li>case studies of best practices</li> </ul> </li> <li>Job aids, prescription pads and infographics</li> <li>Updated guidelines</li> </ul>
<b>Reflective motivation</b>	Interpretability of guidelines, reliance on experience and commodity Perceptions on easiness for patients to start treatment elsewhere (through pharmacies or emergency care) Patients' lack of knowledge on risks and lack of adherence to treatment Family Doctors have an important role as educators	Education Training Education Persuasion Coercion Restriction Education Training Persuasion Education Training Modelling Education Persuasion	<ul style="list-style-type: none"> <li>Guidelines that are more precise</li> <li>Education campaign for the public</li> <li>Greater controls in pharmacies</li> <li>Education campaign for the public</li> <li>Education campaign for the public</li> <li>Education campaign for the public</li> <li>Education campaign for the public</li> </ul>	<ul style="list-style-type: none"> <li>Education campaigns:                             <ul style="list-style-type: none"> <li>For the public:                                     <ul style="list-style-type: none"> <li>TV, radio and social media clips/spots</li> <li>Posters, leaflets, brochures, billboards, bus tails, bus stop posters, interior bus signs</li> <li>Roadshows</li> <li>Theatre plays</li> <li>Interactive website with videos and other information materials, pledging system and competitions (e.g. for creating videos to disseminate educational messages)</li> </ul> </li> <li>Mobile Apps</li> </ul> </li> <li>For health care providers:                             <ul style="list-style-type: none"> <li>Round tables and symposiums</li> <li>Pledge campaigns (e.g. Antibiotic guardian)</li> <li>Training courses</li> </ul> </li> <li>For children and youth:                             <ul style="list-style-type: none"> <li>Games (such as ebug)</li> <li>Special school classes delivered by healthcare professionals or peers (older students)</li> <li>Wet and dry lab activities</li> <li>Cartoon on TV</li> <li>Science-show</li> </ul> </li> <li>For patients:                             <ul style="list-style-type: none"> <li>GPs and pharmacist education sessions</li> <li>Call-back by phone to check adherence to treatment</li> <li>SMS based reminders</li> </ul> </li> <li>Antibiotic packaging with warning messages</li> <li>Greater control mechanisms in pharmacies and communication of findings (to check accuracy of different perceptions)</li> </ul>
<b>Automatic motivation</b>	Maintaining good relations with patients and fear of losing them	Education Persuasion	<ul style="list-style-type: none"> <li>Education campaign for the public</li> </ul>	<ul style="list-style-type: none"> <li>For children and youth:                             <ul style="list-style-type: none"> <li>Games (such as ebug)</li> <li>Special school classes delivered by healthcare professionals or peers (older students)</li> <li>Wet and dry lab activities</li> <li>Cartoon on TV</li> <li>Science-show</li> </ul> </li> <li>For patients:                             <ul style="list-style-type: none"> <li>GPs and pharmacist education sessions</li> <li>Call-back by phone to check adherence to treatment</li> <li>SMS based reminders</li> </ul> </li> <li>Antibiotic packaging with warning messages</li> <li>Greater control mechanisms in pharmacies and communication of findings (to check accuracy of different perceptions)</li> </ul>

**Table 2** (continued)

COM-B Model Domains	Identified factors	Intervention functions	Policy categories and interventions identified by participants	Detailed interventions including examples of additional potential interventions or policies from other settings
<b>Physical opportunity</b>	Lack of access or continuity of care in rural settings COVID pandemic brought higher ABC AMR occurs mostly due to hospital acquired infections Patients may see antibiotics as preventive treatment and obtain medical advice from their social network rather than medical professionals Communities enable action to tackle ABC	Environmental restructuring Education Coercion Restriction Environmental restructuring Education Persuasion Coercion Restriction Environmental restructuring	<ul style="list-style-type: none"> <li>• Treatment individualisation</li> <li>• COVID-19 treatment guidelines</li> <li>• Education campaign for the public</li> </ul>	<ul style="list-style-type: none"> <li>• Mobile clinic or pharmacy services</li> <li>• Making use of eHealth apps to ensure follow-up</li> <li>• Clarity on COVID-19 treatment recommendations</li> <li>• Increased surveillance for emergence of resistance to azithromycin</li> <li>• Antibiotic stewardship interventions for hospital setting</li> </ul>

perceptions of antibiotic consumption and AMR, the interpretability of guidelines and the need to rely on experience as well as potential ‘commodity’ of doctors to prescribe antibiotics. Participants suggested interventions such as periodic updates with statistics -judged jointly with diagnosis, and updating of guidelines. Other interventions that have been implemented in different settings and that could enhance the relevant psychological capabilities are the supplying of job aids, prescription pads and infographics for a quicker identification of relevant information [28, 31]. Surprisingly, the interviews did not reveal particular concerns with the time doctors can dedicate to their patients’ consultations. Considering the Romanian context and the doctors’ exodus to other European countries, this could have emerged as a barrier to providing patient counselling and education. In Romania, there are approximately 63 000 doctors and of these 14 000 are family doctors [13]. Since joining the EU in 2007, there has been a significant brain drain, with many doctors emigrating [14]. This is estimated to bring increasing constraints on providing primary health care. However, the lack of emergence of this finding should be interpreted with caution, as the interviews were time-constrained—this in itself showcasing doctors’ limited availability.

Factors affecting reflective and automatic motivation relate to: i) perceptions on easiness for patients to start treatment elsewhere, ii) their lack of knowledge on risks and lack of adherence to treatment, and iii) the perceived pressure that they may move to another doctor should they feel their needs for antibiotics are not served. One positive factor is that family doctors do see themselves as having an important role as educators. However, some participants didn’t feel that family doctors had a central role, this being more the realm of infectious disease specialists, or doctors that work in the hospital where resistance to antibiotics is more evident. Recent systematic reviews list a series of interventions that could be implemented to conduct educational campaigns in a community setting [28, 29]. These could consist of public facing campaigns (through a series of traditional media channels as well as more interactive ways such as roadshows and theatre plays), competitions, educational campaigns targeting health care providers, including round tables and symposiums, pledge campaigns such as the UK Antibiotic Guardian campaign or more traditional training courses. Promising interventions meant to reach children and youth could consist of games, special school classes delivered by healthcare professionals or peers (older students), wet and dry lab activities, TV cartoons or school-based science-shows [28]. An example of successful game intervention is the ebug—a programme originating from the UK that has been widely

introduced across the EU and has been comprehensively evaluated [32]. Patients that come to ambulatory care could be approached through GPs and pharmacist education sessions, interventions consisting of call-back by phone to check adherence to treatment or short messages based reminders. However, the findings from these systematic reviews showed varying degrees of effectiveness with multifaceted interventions that combine education, restriction and training having a greater impact [28]. As suggested by one participant, antibiotic packaging with warning messages could be explored to flag the risks linked with misuse of antibiotics. Participants also mentioned the need for greater control mechanisms in pharmacies. Previous research in Romania which captured the pharmacists’ perceptions on antibiotic resistance, does support observations that there are cases when pharmacists would make use of the law to dispense antibiotics without a medical prescription [21]. However, the extent and frequency of these practices are not clear. Comparing the perceptions expressed by the pharmacists and the doctors separately, there is a lack of trust in the practices of prescribing and dispensing antibiotics on both sides. Interventions aimed to increase trust could be explored through organising inter-professional collaborations (round-tables, trainings and seminars) and disseminating periodic data on antibiotic prescriptions and sales through pharmacies.

When it comes to the opportunity domain, participants stressed mostly physical opportunity related factors such as lack of access or continuity of care in rural settings, the negative impact of the COVID-19 pandemic, the gravity of hospital acquired infections as well as the enabling power of communities. Interventions to address these factors would require system-based approaches such as ensuring infrastructure to cover the gaps in continuity of care. Mobile clinics or pharmacy services could be explored as well as deploying eHealth solutions that could facilitate monitoring and follow-up. The reported early COVID-19 treatment recommendations, contained a somewhat lack of clarity on the use of azithromycin, leading to it being prescribed in early 2020 which may result in resistance to this antibiotic and potentially infer cross-resistance to other antibiotics. This emphasizes the need for increased surveillance to quickly identify any emergent trends. While the guidelines issued in November 2020 clearly discouraged the use of azithromycin [32], the latest ECDC report shows that Romania ranks first when it comes to total consumption of antibiotics for systemic use within the EU. This data shows a set-back to the levels the country experienced ten years ago [7]. It is difficult to speculate on the exact causes of this rise; however, it is expected that the COVID-19 pandemic played a major role. Potential explanations could be: a slow

dissemination of the updated clinical guidance, perceived secondary bacterial infections in patients with COVID-19 coupled with difficulties in accessing healthcare facilities and laboratories that might have shifted capacities to respond to the pandemic, potential perceived economic hardship experienced by patients which in turn might have deterred doctors and pharmacists to be less strict with prescribing or dispensing of antibiotics in an effort to reduce their hospital-related expenses. These potential pressures could also explain the high consumption of broad-spectrum antibiotics in Romania. Previous research has shown that increasing pressure on family doctors leads to increase in broad-spectrum antibiotics prescriptions [33]. This is a worrying trend as broad-spectrum antibiotics drive AMR more compared to the narrow-spectrum ones [34]. However, with limited practice and capacity to perform antibiograms, it may be difficult for a family doctor to prescribe a narrow-spectrum antibiotic that may not match the causative pathogen, considering the medical risk-assessment as well as cultural considerations related to the doctor-patient relationship. Tackling AMR in hospital settings will require a full antibiotic stewardship package. Data and past cases reported in the Romanian setting do support the perceptions expressed by the family doctors regarding the need to act against AMR in a hospital setting. In addition to the above mentioned ECDC reported data, high profile cases were reported in the press in recent years having to do with substandard quality of disinfectants used in hospitals [35]. Lastly, communities have been identified as enablers to interventions against AMR. Their early involvement is needed in the design, tailoring and piloting of campaigns. However, to ensure this, levers for enabling a participatory community process needs to be further identified with a starting point of agreement on the problem, identification of community needs and 'assets' as they relate to the problem, and consensus on the underlying measures that should be explored.

The overarching theme signalled that there is a perceived lack of patient education leading to unnecessary antibiotic consumption. As patient education is also facilitated by healthcare professionals' interactions, this leads to a potential need for strengthening the doctor-patient relationship. Previous research in Romania flagged that patients may not take for granted a doctor's legitimacy and they tend to seek confirmation regarding the doctor's expertise based on treatment success and feedback from other patients [36]. Patients also increasingly seek additional information online and introduce alternative treatment methods or not follow treatment at all, in an attempt to gain further control on their disease [36]. As eluded by one of the participants, there is an increasing distrust in science that was amplified by the pandemic response

which was challenged by disinformation and enhanced by the increase in social media use. These developments and experiences may transform the norms around the doctor-patient relationship, requiring a higher degree of engagement with the patient to meet the increasing patients' agency. As access to greater amount of information is enabled by technologies, it may become necessary for medical professionals to 'train' patients on how to assess such medical data while ensuring that patients' also understand that greater agency may imply greater responsibility and accountability from their part.

All these considerations need to be underlined by continuous efforts to bridge the 'intention-behaviour gap' [37]—recognising the need to adopt a certain behaviour even if accompanied by a degree of motivation, may not suffice to effect behaviour change if certain barriers are in place. This, corroborated with findings from recent systematic reviews, would suggest the need for deploy a mix of interventions (rather than a short selection) so that factors across the behaviour-change-wheel can be targeted comprehensively.

The challenges highlighted above in regards to the doctor-pharmacist and doctor-patient relationship may also be explored through cultural lenses. Using Hofstede's model of cultural dimensions,<sup>1</sup> Deschepper et al. [38] found indications that countries with high Power Distance (high level of hierarchy) – and high Uncertainty Avoidance (low tolerance for uncertainty and ambiguity)—such as Romania, seem to experience greater antibiotic use. Within the context of the patient-doctor relationship, as well as relations between professionals, the high Power-Distance would translate in deference towards the doctor, and a lesser need for the patients to be involved in medical decision-making [38]. However, our findings would suggest a more complex phenomenon, as while decision-making may be one-sided, there are indications of patient pressure in relation to medical decisions. This together with the emergent distrust in science, may signal a shift of patients type from deferent or ignored towards critical, rather than towards involved.<sup>2</sup> Therefore, it is important to empower doctors to steward shifts in patients' types, by equipping them with correct information and trusted platforms they can recommend to patients that would like to become more health literate. A high Power-Distance and Uncertainty Avoidance, is also

<sup>1</sup> The cultural dimensions in the model are: Power Distance, Individualism, Masculinity, Uncertainty Avoidance and Long-Term Orientation.

<sup>2</sup> Pechère et al. [39] proposed four patients' typologies: i) involved patient—involved in their own medical care, deciding jointly on best approaches; ii) deferent patient—deferent to their doctor and not making joint decisions; iii) ignored patient – reduced interaction with the doctor, feeling ignored but less likely to disagree with the doctor or consider the doctor incompetent; iv) critical patient—doubt the doctor's competence and expertise.

thought to impede doctors from acknowledging situations of uncertainty (e.g. admitting not knowing whether an infection is caused by a virus or a bacteria) out of fear of patient losing confidence in their medical expertise [38]. This dovetails lightly with findings from our study, with doctors being concerned of losing the patients that may choose to visit another doctor that would prescribe antibiotics more willingly. However, this may be more driven by economic considerations rather than fear of being considered less competent. In summary our findings suggest that cultural dimensions may play a role in antibiotic use in Romania, however these should be further explored in studies that would benefit from a larger sample size.

### Methodological considerations

Trustworthiness of this research was sought by enlisting measures to ensure: credibility, transferability, dependability, and confirmability. Credibility was fostered by having interviews performed by an experienced interviewer, a Romanian native speaker familiar with contextual specificities such as social and health system, cultural, economic, policies and political environment. The interviewer did not know any of the participants, sought to create rapport and provided information about herself and the nature of the research. Limitations of the study are linked to the geographical, work sector and age representation of participants as well as constraints with the fact that the research was conducted during the height of the COVID-19 pandemic. While the interviewer was based in Romania, the majority of the interviews, due to the ongoing pandemic, had to be performed over the phone. This posed challenges in terms of reach as well as inability to notice non-verbal communications or cues. Furthermore, in some cases participants mentioned from the start that they cannot devote more than a certain (oftentimes limited) time for the interview. All participants worked as part of their own practice (not part of a private clinic), only one participant was working in rural setting and overall the participants were experienced physicians, therefore the voices of young doctors just entering the field of practice, may not necessarily be reflected in these findings. Transferability was fostered by providing detailed descriptions of the context which would allow other researchers to assess whether findings could be applicable to other settings. Efforts were made to ensure clear methodological descriptions as well as maintenance of study records to allow traceability and repeatability of the study. These were meant to ensure dependability. Confirmability was sought through efforts to foster data

neutrality. The interviewer exhibited deliberate naiveté when conducting the interviews and asked probing questions to ensure accurate understanding. Potential sources of bias could arise from the interviewer's previous research which aimed to capture views on AMR in Romania from the perspective of pharmacists. However, the interview guide was designed to have open-ended questions which would avoid as much as possible the steering of answers.

### Conclusion

The study revealed that family doctors in Romania have varying perceptions on AMR as a national issue. Identified factors contributing to ABC and AMR were related to the perceived behaviour of family doctors or patients as well as to the health system, local contexts and the COVID-19 pandemic. Several potential interventions to tackle these determinant factors emerged, however they seemed to revolve mostly on efforts to educate patients or the public. Participants did not offer conclusive feedback on operationalisation of interventions. This exploratory research provides key perspectives and direction to facilitate further research on potential interventions to be introduced, to successfully address antibiotic resistance in Romanian-or similar settings.

### Abbreviations

AMR	Antimicrobial resistance
ABC	Antibiotic consumption
ECDC	European centre for disease prevention and control

### Supplementary Information

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**Additional file 1.** Annex 1. Interview Guide.

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### Authors' contributions

IG collected and analysed the data, and prepared the manuscript. EP, CSL and AM reviewed the analysis and the manuscript. AM supervised the work on the manuscript. All authors read and approved the final manuscript.

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### Availability of data and materials

The data from interviews used and/or analysed during the current study are available from the corresponding author on reasonable request – respecting the confidentiality and data protection requirements.

## Declarations

### Ethics approval and consent to participate

The research was reviewed and approved by the relevant ethics committee: the National Bioethics Committee of Medicine and Medical Devices in Romania – approval registration no 3SNI from 17.02.2020. All methods were carried out in accordance with relevant guidelines and regulations. Informed consent was obtained from all subjects.

### Consent for publication

Not applicable.

### Competing interests

All authors had no competing interests to declare.

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# LACE Index to Predict the High Risk of 30-Day Readmission in Patients With Acute Myocardial Infarction at a University Affiliated Hospital

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**Background:** The LACE index (length of stay, acuity of admission, comorbidity index, and emergency room visit in the past 6 months) has been used to predict the risk of 30-day readmission after hospital discharge in both medical and surgical patients. This study aimed to utilize the LACE index to predict the risk of 30-day readmission in hospitalized patients with acute myocardial infarction (AMI).

**Methods:** This was a retrospective study. Data were extracted from the hospital's electronic medical records of patients admitted with AMI between 2015 and 2019. LACE index was built on admission patient demographic data, and clinical and laboratory findings during the index of admission. The multivariate logistic regression was performed to determine the association and the risk prediction ability of the LACE index, and 30-day readmission were analyzed by receiver operator characteristic curves with C-statistic.

**Results:** Of the 3,607 patients included in the study, 5.7% (205) were readmitted within 30 days of discharge from the hospital. The adjusted odds ratio based on logistic regression of all baseline variables showed a statistically significant association with the LACE score and revealed an increased risk of readmission within 30 days of hospital discharge. However, patients with high LACE scores ( $\geq 10$ ) had a significantly higher rate of emergency revisits within 30 days from the index discharge than those with low LACE scores. Despite this, analysis of the receiver operating characteristic curve indicated that the LACE index had favorable discrimination ability C-statistic 0.78 (95%CI; 0.75–0.81). The Hosmer–Lemeshow goodness-of-fit test P value was  $p = 0.920$ , indicating that the model was well-calibrated to predict risk of the 30-day readmission.

**Conclusion:** The LACE index demonstrated the good discrimination power to predict the risk of 30-day readmissions for hospitalized patients with AMI. These results can help clinicians to predict the risk of 30-day readmission at the early stage of hospitalization and pay attention during the care of high-risk patients. Future work is to be focused on additional factors to predict the risk of 30-day readmissions; they should be considered to improve the model performance of the LACE index with other acute conditions by using administrative data.

**Keywords:** readmission, acute myocardial infarction, risk assessment, prediction, hospital, quality improvement



## INTRODUCTION

In general, cardiovascular diseases (CVDs) are considered a leading cause of unexpected mortality and morbidity and represent a serious public health concern globally (1–3). Hospital readmissions, especially unplanned ones, are costly for the healthcare industry, and readmission frequency is used to judge hospital quality, as unplanned readmission indicates the failure of the initial intervention (4). The 30-day readmission rates are publicly reported and recent health-reform legislation has endorsed the use of readmission rates for hospital profiling in various countries (5). While some efforts have led to a reduction in cardiovascular disease-related readmissions, it has not been possible to recommend these guidelines widely (1, 6–8). The widely accepted common characteristic of cardiovascular disease is the difficulty in curing it once it has developed, due to the structural dysfunction which cannot be differentiated as emergent and non-emergent AMI (9). AMI continues to be a major cause of mortality and re-hospitalization rates and AMI remains high in the Asia-Pacific population. As per the trends in the prevalence of AMI between 2005 and 2018 reported by the Korea Acute Myocardial Infarction Registry (KAMIR), the mean age and gender ratio gradually increased from 66.9 to 78.0% (10). Moreover, the Korean Acute Heart Failure Registry study found a 90-day readmission rate of 8.1%, a 1-year mortality rate of 15%, and 34.6% of 30-day readmissions (11). AMI is also increasing due to the growth of the aging population. AMI may lead to serious complications, require follow-up medical visits, and repeated readmissions may be a difficult experience for patients and their families (11, 12).

The prediction of the risk for 30-day readmissions has been developed by using the HOSPITAL score (13), PARR-30 in the UK (14), and Patient Admissions Prediction Tool (PAPT) (15). The LACE index is one of the most commonly used indices in the US and Canada (16–20). It was first developed by van Walraven et al. (21) to predict the risk of unplanned readmission or death within 30 days after hospital discharge in medical and surgical patients. The model includes the length of hospitalization stay (L), acuity of the admission (A), comorbidities of patients (C), and the number of emergency department visits in the 6 months before admission (E). Scores range from “0” to “19” and those >10 are considered as high risk for 30-day readmission (22). The higher scores indicate a high risk of readmission. This tool is widely used primarily because its simplicity makes it suitable for day-to-day clinical practice (17–25).

Numerous studies have created models that predict 30-day readmissions by using the LACE index for the prediction of the high risk of 30-day readmissions (16–21, 23). The literature on risk prediction of 30-day readmission emphasizes small patient populations (22–25) or specific patient groups such as those suffering from cardiovascular disease (18–20, 23). Very little known about the LACE index in Asian countries (22, 24). However, no study has been conducted to predict hospital readmission by using the LACE index in South Korea.

Risk prediction of 30-day readmission for patients with AMI could be analyzed through a variety of assessment tools ranging from patient interviews to screening methods, by using a

different set of variables (26–28). Several studies have investigated the predictors, viz., demographic characteristics, admission and discharge predictors, major surgery, comorbidities, length of stay, medications, and special procedures that are associated with 30-day readmissions (29, 30). One of the first steps in reducing 30-day readmissions is understanding and determining the key causes that lead to instances of readmission and developing a predictive model to assess the risk of readmission. Further, predicting the high risk of 30-day readmission would help avoid unplanned 30-day readmission by enabling targeted interventions.

The specific aim of this study was to use the LACE index to predict the risk of 30-day readmissions in AMI patients after discharge from the hospital because there is no prior study on the prediction of 30-day readmission using the LACE index. This study also aims to assess model performance by identifying patients at risk of 30-day readmission and compare the risk prediction ability relating to 60, 90, and 365 days (1 year) hospital readmissions by using the same LACE index.

## METHODS

### Study Design and Setting

A retrospective cohort study design was adopted, and data was derived from January 2015 to December 2019, using the electronic health records of a single university-affiliated hospital in Seoul, Korea. Patients aged 19 years and older, were eligible and hospitalized for AMI as a principal diagnosis and confirmed by using the International Classification of Disease (ICD-10) codes (I20–I25). We excluded patients transferred to other hospitals and those who were not admitted directly from the Emergency Department. We included all patients who were discharged alive from the index hospitalization for the final analysis.

This study protocol was reviewed and approved by the Institutional Review Committee of Yonsei University (4-2021-1047). The ethical consideration of patient consent was waived, and confidentiality was followed by the de-identification of all potentially identifiable data.

### Dependent Variables

Our primary outcome can be defined as hospital readmissions within 30-days for patients diagnosed with AMI as an index of hospitalization. The LACE index score was calculated for each patient, which includes the length of stay (L), acuity of admission (A), comorbidities (C), and emergency visits within the past 6 months. The scoring patterns were calculated and reported in the previous study (16, 17). The length of stay was calculated from the first to the last day of hospitalization and patients admitted to the hospital through the emergency department were identified as acuity of admission, which included patients transferred from the other hospitals through the emergency route. Comorbidities were measured by the Charlson comorbidity index (CCI) score (21), based on the International Classification of Diseases (ICD-10). Emergency visits in the past 6 months were measured, with multiple emergency visits within 24 h being considered as a single visit.

## Independent Variables

The demographic data included patients' age, sex, residence, and insurance types. The discharge data included AMI patients aged 19 and older, those whose sex was considered as either male or female, and those with insurance types such as national health insurance, Medicare, and others. The index of admission types was categorized into three: *via* emergency transfer from other hospitals. The discharge type was normal or with necessary preventive measures and against medical advice or transfer to other facilities such as nursing homes or long-term care centers. In addition, length of stay (LoS), comorbidities by ICD 10 code, primary diagnosis, treatment specialty, admission source, and discharge types were obtained from the hospital EMR data. The 30-day readmission was tracked to identify patients' discharge and readmission history and this report was manually confirmed through chart review.

## Data Analysis

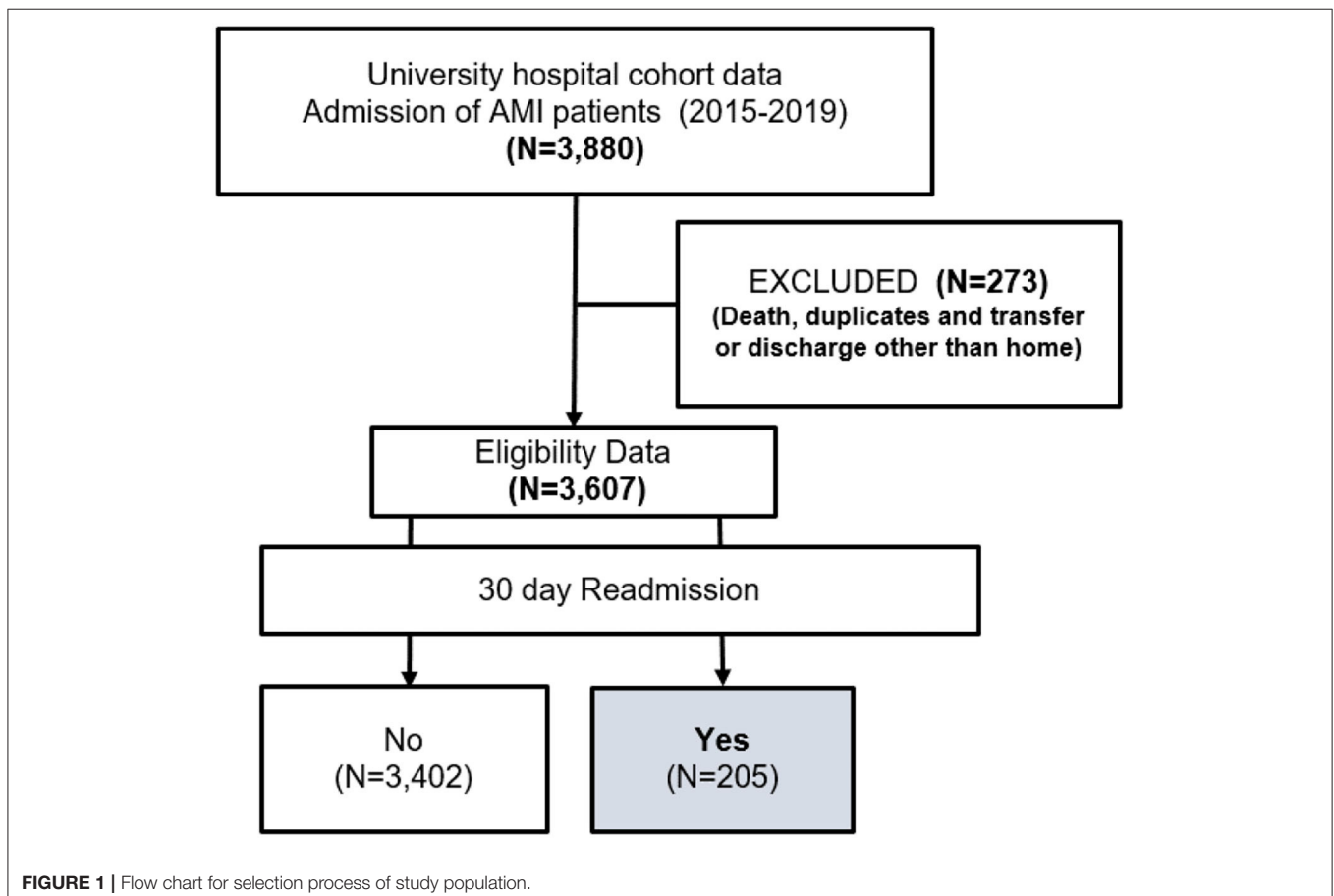
The data were analyzed in three ways. First, we performed the chi-square and univariate comparison between 30-day readmission and no-readmission, frequency, and percentage (*N*, %) for categorical data and mean, standard deviation (*M*, *SD*) for continuous variables of laboratory data. Second, a multivariate logistic regression analysis was performed to identify the factors associated with 30-day readmissions with Odds Ratio (OR; 95%

CI). Third, the prediction ability of the LACE index score was calculated and ROC curves were performed to assess the sensitivity and specificity of the C-statistic prediction model, which ranged from 0.5 (Low discrimination) to 1.0 (Good/high discrimination); it was measured by the area under the curve (AUC). In addition, the Brier score was calibrated to evaluate the accuracy of predicting the risk of 30-day readmission, the values ranging between "0.0" (Perfect accuracy) and "1.0" (perfect inaccuracy). Finally, we investigated a suitable numerical threshold by fitting a logistic regression model for each outcome with dichotomized LACE scores above and below specific thresholds, using sensitivity, specificity, ORs (95% CI), and C-statistics (95% CI) on each outcome's respective receiver operating characteristic (ROC) curve and compared the same with the 60-, 90-, and 1-year readmission as a secondary analysis. *p*-values < 0.05 were considered statistically significant. Statistical analysis was performed using SAS 9.4 (SAS Institute Inc., Cary, NC, USA).

## RESULTS

### Study Participants

The study cohort included a total of 3,607 patients, of whom 205 reported 30-day readmissions among patients hospitalized with AMI during the study period (Figure 1).



## Characteristics of the Patients With 30-Day Readmission vs. Non-Readmission

**Table 1** summarizes the observed frequency (percentage) and mean (standard deviation) baseline data of 30-day readmissions and non-readmissions. More than half the patients were male (58.5%), in the age group of over 65 years (57.1%). Most of them resided in Seoul city (77.1%) and had national health insurance membership (55.6%). The length of stay (LOS) was about 3 days (39.5%), and those admitted through emergency department visits formed 51.7%, while those with two comorbidities (38%)

showed 30-day readmissions. Laboratory findings revealed that patients readmitted within 30-days had lower hemoglobin levels ( $10.6 \pm 9.3$ ;  $p < 0.001$ ) which was significant. However, there were no statistical differences in any other laboratory findings.

## Multivariate Logistic Regression Analysis for 30-Day Readmission in Patients Hospitalized With AMI

In a multivariate logistic regression analysis, risk factors determined to be independently associated with 30-day

**TABLE 1** | Baseline characteristics of 30-day readmission vs. no readmission patients admitted with AMI.

Variables	Characteristics	30-day readmission				p
		Yes (n = 205)		No (n = 3,402)		
		N	%	N	%	
LACE index score	0–4	42	20.5	838	24.6	<0.001
	5–9	71	34.6	1771	52.1	
	≥10	92	44.9	793	23.3	
Age (years)	<34 years	12	5.9	591	17.4	<0.001
	35–64	76	37.1	896	26.3	
	≥65	117	57.1	1915	56.3	
Sex	Male	120	58.5	1,928	56.7	<0.001
	Female	85	41.5	1,474	43.3	
Residence	Seoul (capital area)	158	77.1	2,163	63.6	<0.001
	Metropolitan cities	47	22.9	905	26.6	
	Other cities	0	0.0	334	9.8	
Health insurance	NHI	114	55.6	2,796	82.2	0.008
	Medicare	86	42.0	486	14.3	
	Others	5	2.4	120	3.5	
Length of stay	≤2	49	23.9	795	23.4	0.114
	3	81	39.5	908	26.7	
	4	22	10.7	708	20.8	
	5	24	11.7	622	18.3	
	6	18	8.8	221	6.5	
Admission Route	ER	106	51.7	2,191	64.4	<0.001
	Transfer from other hospital via ER	99	48.3	711	35.6	
Comorbidities <sup>®</sup> (CCI score)	1	68	33.2	1,865	54.8	0.023
	2	78	38.0	1,023	30.1	
	≥3	59	28.8	514	15.1	
Laboratory findings (M ± SD)	SBP (mmHg)		125.1 (15.6)		120.8 (17.5)	0.191
	Hemoglobin, mg/dL		10.6 (9.3)		11.4 (9.8)	<0.001
	WBC, ×10 <sup>3</sup> /UL		3.6 (1.1)		5.8 (3.0)	0.441
	Platelet, ×10 <sup>3</sup> /μL		223.1 (99.8)		225.6 (111.8)	0.418
	Creatinine, mg/DI		1.65 (2.4)		1.2 (1.1)	0.541
	Potassium, mmol/L		3.9 (0.5)		4.04 (3.2)	0.842
	Sodium, mmol/L		137.2 (4.5)		139.5 (4.1)	0.691
	Estimated GFR (mL/min/m <sup>2</sup> )		39 (25.8)		41 (28)	0.511
Discharge type	Normal	38	18.5	2,988	87.8	0.121
	Others*	167	81.5	414	12.2	

N (%), number (Percentage); M (SD), Mean ± standard deviation; p-value, chi-square test; NHI, National health insurance; ER, Emergency route; CCI<sup>®</sup>, Charlson comorbidity index (1, 2, ≥3 represent the number of comorbidities); WBC, White blood cell; GFR, Glomerular filtration rate; OP, Outpatient; \*Home with support services, transfer to long-term care/other institution, Left against medical advice.

readmissions are shown in **Table 2**. Older patients aged < 65 years (OR, 8.15; 95% CI, 4.07–6.24), who were male (OR, 1.07; 95% CI, 1.06–1.07), had Medicare insurance (OR, 1.07; 95% CI, 1.00–1.11), admitted through the emergency route (OR, 1.45; 95% CI, 1.42–1.54), and belonged to the other discharge types (OR, 1.09; 95% CI, 1.04–1.14) were more likely to have 30-day readmission, after controlling potential confounders. In addition, LACE index risk scores  $\geq 10$  (OR, 2.71; 95% CI, 1.03–4.37) were highly associated with 30-day readmission than lower LACE scores (0–4 and 5–9).

The association between the different LACE variables was found to highly predict the risk of 30-day readmission; the length of stay (OR, 2.01; 95% CI, 1.35–2.98), index of admission (OR, 1.21; 95% CI, 1.01–1.44), comorbidity (OR, 1.72; 95% CI, 1.16–2.55), and the number of emergency visits in the last 6 months (OR, 1.61; 95% CI, 1.14–2.52) were statistically significant at  $p < 0.001$  level.

### Sensitivity Analysis

The discrimination ability of the model for risk prediction of 30-day readmission in **Figure 2** shows a modest performance of the LACE index in risk prediction for 30-day readmission with a C-statistic of 0.78 (95% CI 0.75–0.81). The ROC analysis outcome of 30-day readmissions is shown in an AUC curve (**Figure 2**). The Brier score for the LACE score in this setting was 0.042, indicating overall good performance and the Hosmer-Lemeshow goodness-of-fit test  $p$ -value was  $p = 0.920$ , indicating that the model was well-calibrated; this was consistent with the calibration plot (**Figure 3**). These findings indicated that the LACE index model has a favorable risk prediction ability for 30-day readmission of patients hospitalized with AMI.

### Secondary Analysis

**Figure 3** illustrates the frequency distribution of readmissions based on the time duration calculated as a secondary analysis. In addition, a new prediction model analysis of the LACE index was performed with different combinations of readmissions for 60 days, 90 days, and 1 year as shown in **Table 3**, as it was not relevant to our present cohort study. However, these findings were varied in the prediction ability of the LACE index; the C-statistic for each model of readmissions was: 60 days = 0.75 (95% CI, 0.71–0.79), 90 days = 0.60 (95% CI, 0.58–0.62), and 1 year = 0.60 (95% CI, 0.56–0.64). The results demonstrated that the LACE index is better in predicting the risk of 30- and 60-days readmissions than 90 days and 1-year readmissions (**Figure 4**).

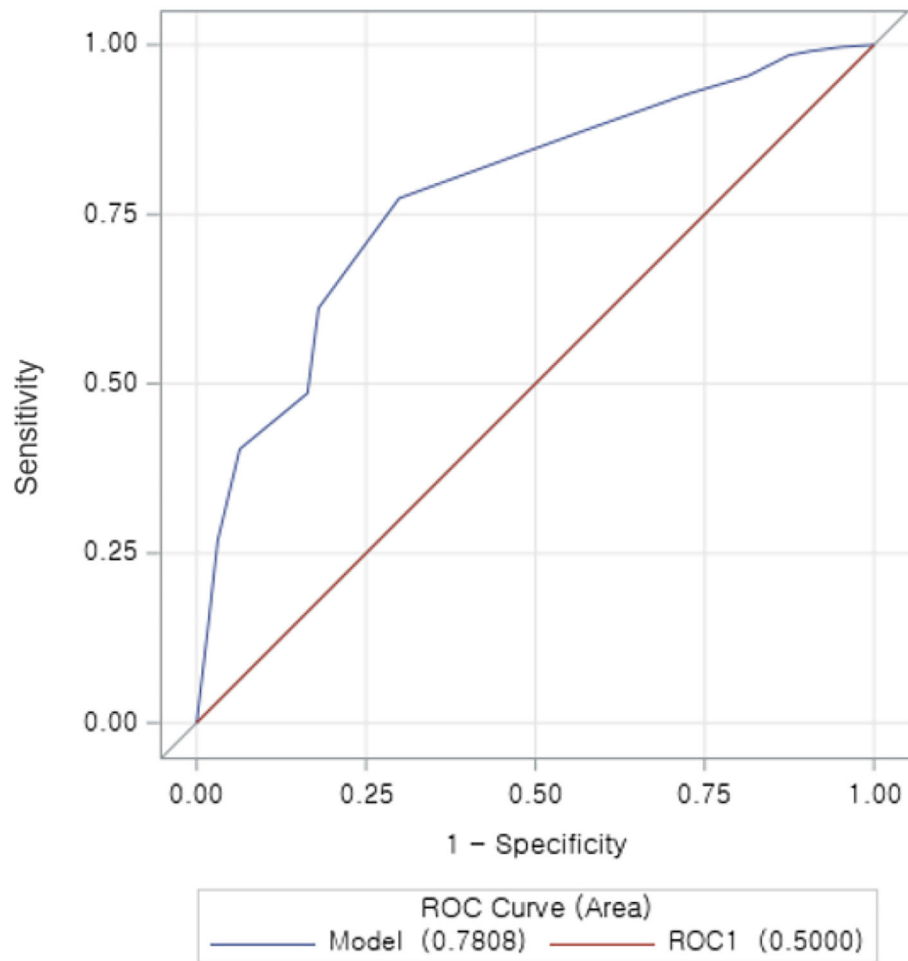
### DISCUSSION

This study aimed to predict the risk of 30-day readmissions by using the LACE index score and validated models for patients hospitalized with AMI. A systematic review was retrieved from 16 unique LACE index articles to predict the risk for 30-day readmissions in specific diseases and population groups in limited countries prior to this study; there were no such studies found in South Korea. The overall 30-day readmission rate was lower than the reported 15.5–15.9% (7, 26, 27). However, it is difficult to compare the studies directly because the published studies used Medicare's fee-for-service claims data in the US and included only elderly Medicare patients. In addition, the variation and internal protocol in hospitals' systems across the nation could account for the changes in the 30-day readmission rate. Our study found that men were 13% more likely to have 30-day readmission than women. This is similar to an earlier retrospective study conducted in patients with heart failure,

**TABLE 2** | Multivariate logistic regression analysis for 30-day readmission in patients hospitalized with AMI ( $N = 205$ ).

Variables	Characteristics	30-day readmissions (yes)		
		OR	95% CI	$p$
Age, years	19–44	1.00		
	45–64	3.15	0.86	6.17
	$\geq 65$	5.15	4.07	6.24
Sex	Male	1.07	1.06	1.07
	Female	1.00		
Health insurance	NHI	1.00		
	Medicare	1.07	1.00	1.11
	Others	0.98	0.85	1.13
Admission route	ER	1.45	1.42	1.54
	Transfer from other hospital via ER	1.00		
Discharge type	Normal	1.00		
	Others*	1.09	1.04	1.14
LACE index_score	0–4	1.00		
	5–9	1.13	1.11	1.15
	$\geq 10$	2.71	1.03	4.37

OR, odds ratio; CI, confidence interval; AMI, Acute myocardial infarction; IQR, Interquartile range; NHI, National health insurance; ER, Emergency visit; op, Outpatient visit; \*Home with support services, transfer to long-term care/other institution, Left against medical advice.



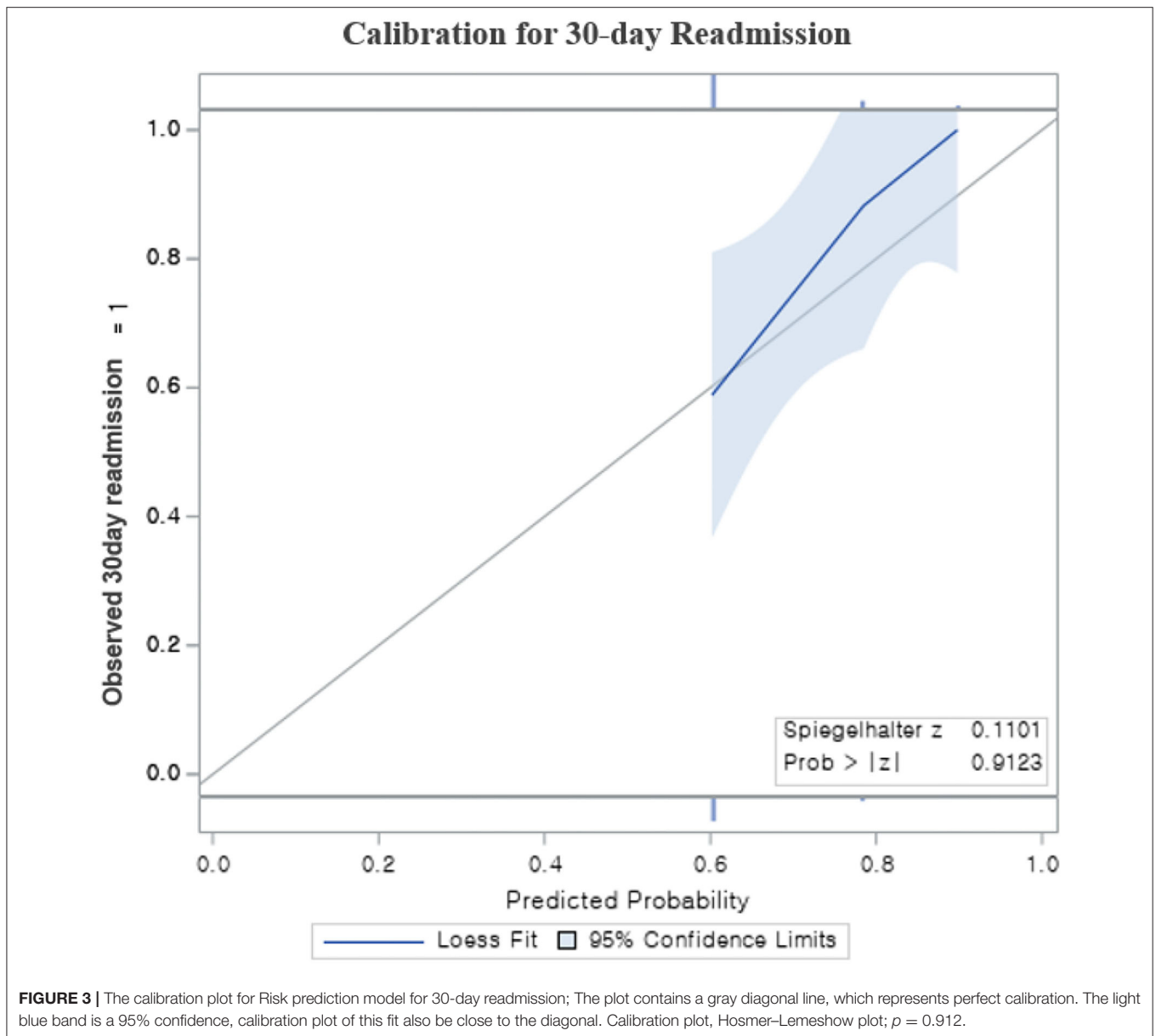
**FIGURE 2** | Receiver operator characteristic (ROC) curve for the LACE index in hospitalized AMI patients. The ROC curve illustrates the risk prediction for 30-day readmission at different cutoff points. With increased sensitivity and decreased specificity. The area under the curve (AUC), which is equal to the C-statistic (0.78), indicating a favorable model to predict the risk of 30 days readmission in patients hospitalized with AMI.

COPD, and all-cause readmissions predicted by using the LACE index (17–20, 23, 24).

We also found that patients discharged for other reasons such as against medical advice or voluntarily discharged were more prone to 30-day readmissions, compared to those discharged normally. This finding is consistent with other studies (8–12) and the performance of the LACE index was found to vary with disease conditions (16–19). However, patients' discharge destination showed that those discharged directly to their homes were at a greater risk of 30-day readmission than those transferred to inpatient rehabilitation or other care, including home care service. This concurred with another study (9), in addition to another version of a competing risk issue previously mentioned. An alternative interpretation is that patients discharged home are less likely to die before readmission than those discharged to Skilled Nursing Facilities (SNFs). Patients discharged to SNFs can also, to some extent, get the care they need in the case of a potential exacerbation of their underlying condition, diverting some potential readmissions,

whereas patients discharged home may not be able to access that care as easily, without going to the hospital. This would also depend on which post-discharge case management programs are in place. Therefore, post-discharge interventions and resources are required for the patients who are discharged directly to their homes, as it would help in preventing or reducing 30-day readmissions.

A significant finding of this study was that 30-day readmissions were predominantly related to socioeconomic factors, rather than clinical findings of the index of admission. This was consistent with other studies with different disease conditions, where the clinical findings had least or not been considered (5, 8, 10–12, 14, 16–19, 27). Therefore, the prediction of readmission for acute care suggests that the attention to clinical findings would be considered in long-term care than in acute care settings. Similar to other reports on CVD-related 30-day readmission rates among Medicare beneficiaries, this study found higher 30-day readmission rates among men, patients aged < 65 years,



**FIGURE 3 |** The calibration plot for Risk prediction model for 30-day readmission; The plot contains a gray diagonal line, which represents perfect calibration. The light blue band is a 95% confidence, calibration plot of this fit also be close to the diagonal. Calibration plot, Hosmer–Lemeshow plot;  $p = 0.912$ .

**TABLE 3 |** Secondary analysis of comparison between 30-day readmission and 60-, 90-, and 365-days (1 year) readmissions of patients hospitalized with AMI.

	Hospital readmissions		
	60-days	90-days	365-days (1 year)
AUC	0.75	0.60	0.60
95% CI	0.71–0.79	0.58–0.62	0.56–0.64
$p$	<0.001	<0.001	<0.001

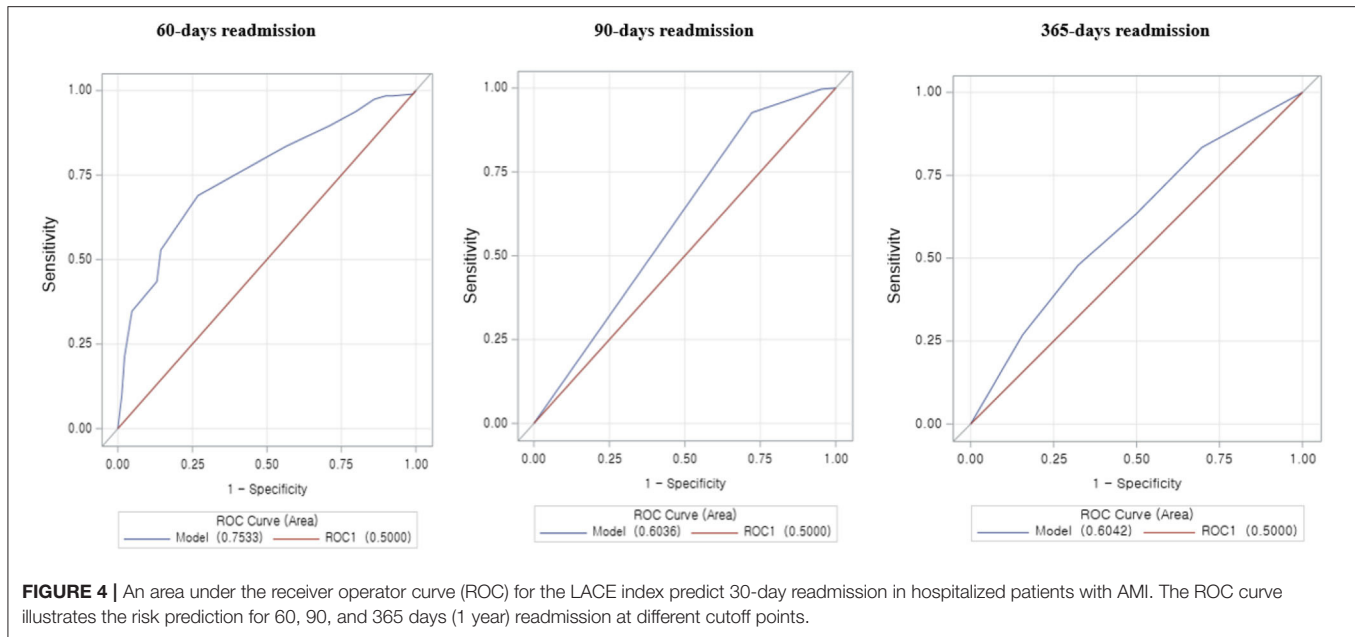
AUC, Area under the curve.

those from lower-income households, and those with multiple comorbidities (12, 18–20, 26, 27, 30).

Hence, it is hypothesized that fluctuations in emergency room visit trends could be a possible cause of the variations in

readmission observed in the later years. Studies have reported various factors contributing to 30-day readmission, including complications of inpatient treatment, irrelevant coordination of care, inferior quality of care, ineffective medication advice, discharge education, and follow-up (8, 28, 29). In contrast to the LACE index, the length of stay and acuity of admission were not associated with the risk of 30-day readmission, after adjusting the covariates in the multivariate logistic regression model. It is possible that the duration of admission was affected by other factors such as demographic characteristics and did not reflect the severity of illness entirely in this cohort study.

Our previous literature review identified that several other factors such as age, comorbidity index, and emergency department visits in the past 6 months were significant in the prediction of 30-day readmission risk (21). In all the predictive models, AMI was statistically significant. This is altogether found



in the chronic nature of readmissions among patients with cardiovascular diseases (18–21, 23, 29). Our study found results from 2015 to 2019 with an absolute possibility of risk prediction for 30-day AMI readmissions with a LACE score of more than 10. The studies of Medicare insurance have suggested similar results, that implementation of the LACE index is associated with a decrease in cardiovascular disease readmissions. Some studies have reported a decline in 30-day readmissions after the LACE index implementation phase (18–25).

The LACE index allows clinicians to calculate an individual's unique risk of 30-day readmission quickly and accurately, enabling improved coordination of care between healthcare professionals and the implementation of various strategies to prevent readmissions among high-risk patients. Reducing readmissions not only reduces healthcare expenditure but most importantly, also improves patient outcomes and satisfaction. Readmissions are not only inconvenient and costly to the patient but also come with inherent risks such as hospital-acquired infections, which impact patient outcomes negatively. Therefore, this study suggests using the LACE index, as it would be helpful for physicians to make better clinical decisions about the duration and aggressiveness of patient treatment and management and for curtailing premature discharge for patients with high readmission risk.

## CONCLUSION

We have used the novel findings of an important tool the LACE index with associated factors—to predict the 30-day readmissions, for the first time in South Korea. LACE can be computed without the aid of special software and does not require complex information such as community-specific rates of admission or economic status. Given its ease of use at the bedside, LACE is commonly applied to risk-stratify patients

hospitalized with medical illnesses. Therefore, focusing on the LACE index is recommended to predict the risk of 30-day readmissions as it is critical for reducing the future readmission burden of patients with acute CVDs. In addition, constant follow-up of the AMI patients may also be needed to reduce the readmission risks of those directly discharged to their homes. The findings of this study would be communicated to healthcare managers so that they can implement policies to use the LACE index to easily predict the risk of early readmissions and avoid unnecessary medical expenditure. The findings will assist in targeting future interventions to predict 30-day readmissions and should be expanded by using national administrative data that includes prospective design, more periods with all the causes of 30-day readmissions, and additional factors, to get a better understanding of the association between 30-day readmissions and cost-effectiveness analysis by using the LACE index and to demonstrate the lag effects of readmission rates on operating margin.

## LIMITATIONS

This study has some limitations. First, the patients were selected from a single hospital in the metropolitan city, and its findings are not intended to be generalized to other areas in Korea. Further work is needed to characterize whether certain ICD-10-AMI codes represent 30-day readmission that could be prevented through improved clinical-based care or healthcare systems. Moreover, our study was designed with observations and used the retrospective cohort data of individual hospital data, including laboratory data. Causation must be considered for generalizing the findings, as there might be unnoticed variables of laboratory data as confounding variables. Second, the cohort data of patients hospitalized with AMI between 2015 and 2019 was unique and changes were made to clinical

guidelines, in particular to the provision of acute services after the introduction of cardiovascular conditions. We did not focus on the spectrum of NSTEMI and STEMI. In particular, we do not know the baseline and the treatment that will be initiated in post-discharge management. Time-varying covariates do not yield the perfect prediction model, which limits the prediction of 30-day readmission risk in some extended clinical management in treatment (31). We were not able to address the details of the TRIPOD statement (32). However, we have included the TROPID checklist as a **Supplementary Material** in this study. Therefore, these issues should be addressed in future studies for better implementation of the predictive model for further consideration. However, these results remain novel because, for the first time, reliable data has been offered on 30-day readmissions after the hospital discharge of patients with AMI in Korea.

## DATA AVAILABILITY STATEMENT

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

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## ETHICS STATEMENT

The studies involving human participants were reviewed and approved by Yonsei University (IRB: 4-2021-1047: 002). The patients/participants provided their written informed consent to participate in this study.

## AUTHOR CONTRIBUTIONS

VR, TK, and SL: conceptualization. JS, VR, and WH: data curation and formal analysis. VR and JS: investigation. JS, VR, WH, SL, and TK: methodology. SL and TK: resources and supervision. VR: writing—original draft. JS, SL, and TK: writing—review and editing. All authors contributed to the article and approved the submitted version.

## SUPPLEMENTARY MATERIAL

The Supplementary Material for this article can be found online at: <https://www.frontiersin.org/articles/10.3389/fcvm.2022.925965/full#supplementary-material>

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# Differences in the impact of precarious employment on health across population subgroups: a scoping review

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## Abstract

**Aim:** Precarious employment is known to be detrimental to health, and some population subgroups (young individuals, migrant workers, and females) are at higher risk of precarious employment. However, it is not known if the risk to poor health outcomes is consistent across population subgroups. This scoping review explores differential impacts of precarious employment on health.

**Methods:** Relevant studies published between 2009 and February 2019 were identified across PubMed, OVID Medline, PsycINFO, and Scopus. Articles were included if (1) they presented original data, (2) examined precarious employment within one of the subpopulations of interest, and (3) examined health outcomes.

**Results:** Searches yielded 279 unique results, of which 14 met the eligibility criteria. Of the included studies, 12 studies examined differences between gender, 3 examined the health impacts on young individuals, and 3 examined the health of migrant workers. Mental health was explored in nine studies, general health in four studies, and mortality in two studies.

**Conclusion:** Mental health was generally poorer in both male and female employees as a result of precarious employment, and males were also at higher risk of mortality. There was limited evidence that met our inclusion criteria, examining the health impacts on young individuals or migrant workers.

## INTRODUCTION

The association between better health outcomes and good quality, stable employment is well established,<sup>1,2</sup> and good employment is one of the essential conditions for health equity.<sup>3</sup> In recent decades, employment trends have seen a marked increase in flexible, non-standard arrangements, contributing to reduced job security, reduced income security, and increased temporary contracts.<sup>4-6</sup> Since 1995, more than half of the new jobs created in the European Union have been part-time, non-contracted, or insecure positions.<sup>3,5</sup> There are a number of factors that have contributed towards changes in the trends in employment, including technological advancements and globalisation contributing to the worldwide mobility of workers and capital,<sup>4,7,8</sup>

a declining influence of unions,<sup>6</sup> diminishing social protection including labour market reform,<sup>6,9</sup> and economic downturn caused by recession and austerity.<sup>5,9</sup> Furthermore, recent global recessions and associated high unemployment rates have disempowered workers<sup>4,10</sup> and seen the increase of precarious employment arrangements. The Covid-19 pandemic will have undoubtedly worsened many of these trends.

There is no single definition of precarious employment, but it is recognised as a multidimensional construct encompassing dimensions of employment insecurity, incorporating both length of contract and perceptions of job insecurity; individualised bargaining; relations between workers and employers; low wages and economic deprivation;

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limited workplace rights and social protection; and powerlessness to exercise legally granted workplace rights.<sup>5,11</sup> Some population subgroups, namely younger people, migrant workers, and women, are more likely to be in precarious employment.<sup>8,12–14</sup> Young adults are particularly vulnerable in the labour market, as they lack work experience, qualifications, and available employment opportunities.<sup>15</sup> Precarious employment conditions expose younger individuals to health inequalities from constant transition in labour market activity; in particular, impact on mental health and increased health risk behaviours, likely contributed to by the lack of economic and social benefits.<sup>15</sup> Migrant workers are also at increased risk of precarious employment arrangements; they are subject to discrimination and exploitation, further adversely impacting on mental wellbeing.<sup>7,16</sup> Women are more often employed in precarious, low-paying occupations, including those within the care sector, than their male counterparts.<sup>5,17</sup>

Despite relying heavily on one-dimensional constructs such as temporary contracts or the perception of job insecurity,<sup>5</sup> the majority of the literature suggests that compared to permanent employment contracts, precarious employment arrangements can have a negative impact on the general, physical, and mental health of individuals.<sup>1,3,18,19</sup> The effect can also extend beyond the individual, to indirectly impact on the household and family unit, through stress and material deprivation.<sup>20,21</sup> The quality of the local labour market can also affect the wider community through reduced spending power and decline in community participation.<sup>5,22</sup> Considering the wider-reaching social and wellbeing implications of precarious employment, it has been suggested that precarious employment is now an emerging social determinant of health.<sup>6</sup>

It is relatively unknown whether the association(s) between precarious employment and poor health is the same across groups at risk of precarious employment, that is, is the health impact of precarious employment worse for some than others. Over a decade ago, it was reported that the health of women,

although disproportionately affected by precarious employment, is often neglected in research studies.<sup>17</sup> This is a scoping review to explore the current evidence base and whether the differences in health outcomes are fully explored across population subgroups at the greatest risk of exposure to precarious employment (young individuals, migrant workers, and women).

### METHODS

#### Search strategy and eligibility criteria

The methodology adopted in this study followed the framework for scoping reviews outlined by Arksey and O'Malley.<sup>23</sup> For this review, articles were included if (1) they presented original data; (2) examined precarious employment within one of the subpopulations of interest (younger people, migrant workers, women); and (3) examined differences in health outcomes. The following limits were also applied as eligibility criteria: full texts written in English and published (including online ahead of print) from 2009 to February 2019. Literature searches were performed in March 2019 and four electronic databases (PubMed, OVID Medline, PsycINFO, and Scopus) were used as sources. In addition to these sources, manual searches were undertaken on the reference lists of previous reviews on the topic area. The search keywords, Medical Subject Headings (MeSH) terminology, and search strings were agreed between the authors and verified by the Public Health Wales Observatory Evidence Service. In brief, the search strategy used for this review was as follows ('employment' OR 'work') AND (precarious OR casual OR temporary OR zero hours) AND ('health') AND ('socioeconomic factors' OR inequalit\*).

#### Study selection and summary of results

Figure 1 illustrates an overview of the study selection process. The initial database searches yielded 353 titles, and an additional 13 articles were retrieved through manual searches. Following the removal of duplicate articles, 279 unique results remained.

At least two of the authors independently reviewed the titles and abstracts of the unique articles and excluded any that did not meet the eligibility criteria. The opinion of a third author was sought to resolve disagreements on the inclusion of articles. After title and abstract screening, full-text reviews were undertaken on 49 articles, again by two reviewers, of which 34 were excluded, leaving 15 studies remaining for quality appraisal. The quality of the studies was assessed by two reviewers using the Joanna Briggs Institute Critical Appraisal checklists for cross-sectional and cohort studies as appropriate.<sup>24</sup> One study was subsequently excluded because of quality concerns, leaving 14 studies for inclusion in this review. The key observations from the eligible studies are presented as a narrative summary and focus on the three subpopulations disproportionately at risk of exposure to precarious employment.

### RESULTS

#### Study characteristics

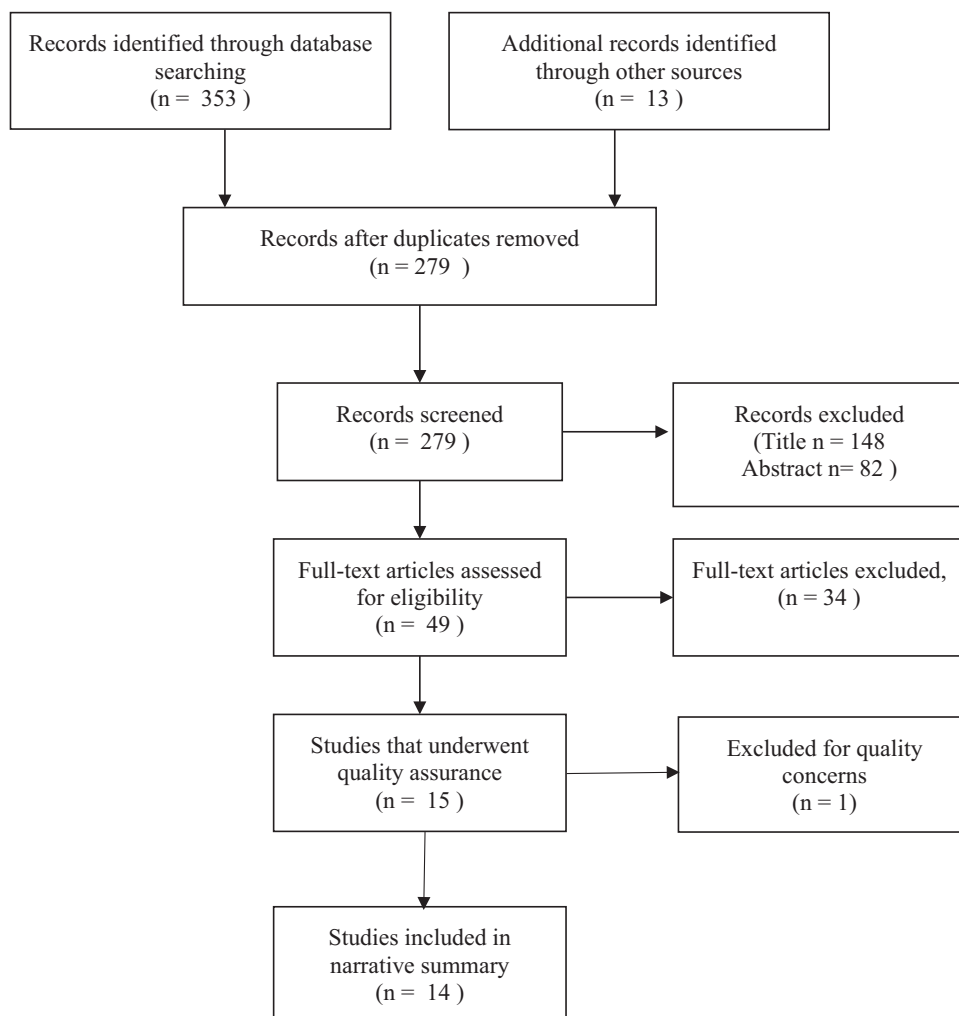
The majority of the studies (11 out of 14) were undertaken in Western Europe; two of the studies were undertaken in South Asia (Japan and South Korea) and the remaining study was undertaken in the Australian population. All the studies were observational, four were cross-sectional<sup>25–28</sup> and the remaining ten were cohort studies (Table 1). The data sources for the studies ranged from country-specific postal or repeated surveys, study-specific questionnaires, or data from existing large-scale, regional surveys (Table 1). In regard to the quality of the studies, there were no issues with any of the cross-sectional studies; however, there were some minor queries about the follow-up procedures in some of the cohort studies (Table 1).

More specifically, it was unclear which mechanisms were used to re-contact or allow for non-respondents in some studies which relied on repeat survey data collection.

#### Health outcomes considered

Three health outcomes were explored in the studies: general health, mental

Figure 1.

**PRISMA diagram of study selection**

wellbeing, and mortality. General health outcomes were included in four studies<sup>25,29–31</sup> and were self-reported using a variety of measures; two studies<sup>25,31</sup> used a question recommended by the World Health Organization, one study<sup>30</sup> used the General Health Questionnaire-12 (GHQ-12),<sup>30</sup> and the remaining study a nationally validated measure.<sup>29</sup> Mental wellbeing outcomes were included in nine of the studies.<sup>25–28,32–36</sup> Mental health was assessed through validated self-reported measures; the GHQ-12 in four studies,<sup>25,27,32,33</sup> the Mental Health Inventory (MHI) derived from the Short Form-36 (SF-36) health questionnaire was used in three studies,<sup>26,28,34</sup> the

11-question Centers for Epidemiological Studies Depression (CES-D) Scale in one study,<sup>36</sup> and the shortened Kessler Psychological Distress (K6) scale in the remaining study.<sup>35</sup> Some of these studies also used a ‘threshold’ score to be indicative of clinical measures such as psychological distress, depression, or anxiety.<sup>25,27,32,33,35,36</sup> Finally, mortality was considered in the remaining two studies,<sup>37,38</sup> one of these studies examined all-cause mortality, non-violent mortality, and violent causes<sup>38</sup> and the other study explored premature mortality.<sup>37</sup> Both of these studies<sup>37,38</sup> assessed mortality using the national (France) computerised databases for recording deaths.

### Dimensions and definitions of precarious employment

The definitions of precarious employment (or exposure) used in each of the studies are outlined in Table 1. Precarious employment was defined slightly differently in all studies and despite being a multidimensional construct,<sup>5,11</sup> multiple dimensions of precarious employment were only considered in three of the studies,<sup>28,32,36</sup> and job insecurity was only explicitly considered in one of these;<sup>28</sup> however, temporariness of contract was a constant factor (Table 1). There were differences in the approach to defining employment groups across the studies. Two studies included part-time workers as being in precarious employment.<sup>35,36</sup>

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Table 1.

Overview of included studies						
Author, country	Study design	Participants (% males)	Data source	Aim/research question	Exposure	Quality <sup>a</sup>
Garnivet et al., <sup>32</sup> Sweden	Cohort	1135 (40.6% males)	Scania Public Health Cohort	Investigate the associations between precarious employment situations and mental health later in life among young adults aged 18–34 years.	Precarious employment situation. Defined as: (1) contingent work with a perceived risk of future unemployment, (2) previous unemployment, (3) those with moderate to high self-rated risk of future unemployment, and (4) presently unemployed.	Minor concern on follow-up methods
Fiori et al., <sup>26</sup> Italy	Cross-sectional	20,432 (no details provided on gender split)	Health Conditions and Access to Health Services Survey	Is there a significant relationship between greater employment insecurity and worse mental health among the youth labour force in Italy?	Employment insecurity (fixed-term contract; atypical contract).	No concerns
Julia et al., <sup>28</sup> Spain	Cross-sectional	4430 (56.2% males)	Second Psychosocial Work Environment Survey	To test the existence of a general precarisation of the Spanish labour market and its association with mental health for different types of contract.	Temporary contract and employment calculated as high precariousness (EPRES $\geq$ 2).	No concerns
Kachi et al., <sup>35</sup> Japan	Cohort	15,222 (55.7% males)	Longitudinal Survey of Middle-aged and Elderly Persons	Examine whether precarious employment increases the risk of serious psychological distress.	Precarious employment (part-time employee; temporary agency worker; fixed-term contract).	Minor concern on follow-up methods
Khiat et al., <sup>38</sup> France	Cohort	2500 (56.1% males)	Lorhandicap Survey	Is the mortality of temporary workers higher than that of workers with permanent employment?	Temporary employment.	Minor concern on follow-up methods
Kim et al., <sup>36</sup> South Korea	Cohort	2891 (64.8% males)	Korean Welfare Panel Study	Examined how change in employment status is related to new-onset depressive symptoms and whether this association differs by gender.	Precarious workers. Those that did not meet all four of the following criteria: (1) directly hired by their employers; (2) full-time workers; (3) no fixed term in their employment contract; (4) a high probability of maintaining their current job.	Minor concern on follow-up methods
Minelli et al., <sup>29</sup> Italy	Cohort	37,782 observations (49.2% males)	Survey on Household Income and Wealth	Offer evidence on the relationship between self-reported health and employment status.	Temporary workers. Comprises job contracts such as apprenticeships, on-project jobs, and seasonal jobs.	Minor concern on follow-up methods
Niedhammer et al., <sup>37</sup> France	Cohort	4118 (53.2% males)	Lorhandicap Survey	Analyse the association between SES as measured using occupation and two measures of all-cause mortality, premature and total mortality.	Temporary contract	Minor concern on follow-up methods

(Continued)

## Differences in the impact of precarious employment on health across population subgroups: a scoping review

Table 1. (Continued)

Overview of included studies						
Author, country	Study design	Participants (% males)	Data source	Aim/research question	Exposure	Quality <sup>a</sup>
Pirani and Salvini, <sup>31</sup> Italy	Cohort	1831 (64.5% males)	Italian EU-SILC panel 2007–2010	Are (Italian) workers on temporary contracts more likely to suffer from poor health than those with permanent jobs?	Temporary employment (fixed-term contract)	Minor concern on follow-up methods
Richardson et al., <sup>34</sup> Australia	Cohort	38,369 observations (49.5% males)	Household Income and Labour Dynamics in Australia (HILDA) survey	Investigate the impacts on mental health of employment on these. Terms (casual, fixed-term) and of unemployment.	Casual employment or fixed-term contract	Minor concern on follow-up methods
Robert et al., <sup>33</sup> Spain	Cohort	214 (53.7% males)	ITSAL I and II (Immigration, Labour and Health) Project	Evaluates the influence of changes in employment conditions on the incidence of poor mental health of immigrant workers (in Spain), after a period of 3 years.	Temporary contract	Minor concern on follow-up methods
Samuelsson et al., <sup>30</sup> Sweden	Cohort	877 (52.2% males)	Questionnaire data was used from a 27-year follow-up study of school-leavers carried out in Luleå in the north of Sweden	To investigate whether type of employment was related to work characteristics and health status at age 42.	Temporary employment. Measure by six questions on: project/object, substitute, probationary, on demand, seasonal, and other fixed-term contracts.	Minor concern on follow-up methods
Sidorchuk et al., <sup>27</sup> Sweden	Cross-sectional	51,118 (52.3% males)	Stockholm County Public Health Surveys (2002, 2006, and 2010)	Investigate whether the association between employment status and psychological distress differs between immigrants and (Swedish-born).	Temporary employment	No concerns
Sousa et al., <sup>25</sup> Spain	Cross-sectional	2358 (57.3% males)	ITSAL I and II (Immigration, Labour and Health) Project	Analyse the relationship of legal status and employment conditions with health indicators in foreign born and (Spanish-born workers).	Temporary contract	No concerns

EPRES: Employment Precariousness Scale; EU-SILC: European Union Statistics on Income and Living Conditions; HILDA: Household Income and Labour Dynamics in Australia; SES: socioeconomic status.

<sup>a</sup>The quality of the studies was assessed using the Joanna Briggs Institute Critical Appraisal checklists for cross-sectional and cohort studies as appropriate.<sup>24</sup>

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In some studies, self-employed individuals were excluded;<sup>28,34</sup> some studies combined self-employed and permanent employees together;<sup>27,29,38</sup> and others treated self-employed individuals as a separate employment category.<sup>30</sup> Where unemployed individuals were included, the majority of studies analysed this group as a comparator.<sup>26,27,29,33,34,36,38</sup> One study included unemployment within the precarious employment group.<sup>32</sup>

### Inequalities explored

Of the 14 studies included in the synthesis, differences in health outcomes by gender (Table 2) were most frequently identified by authors and discussed in all but two of the studies.<sup>32,33</sup>

The exposure of precarious employment on health outcomes experienced by younger individuals (Table 3) was considered in three studies<sup>26,29,32</sup> and only three studies<sup>25,27,33</sup> considered health outcomes for migrant workers (Table 4).

### Identification of confounders and covariates

The papers included in this summary all list a number of confounders or covariates, which were considered and adjusted for in the statistical models. Education, gender, deprivation, and financial situation were identified as potential confounders in over half of the included studies and some of the studies<sup>28,30,31,33,35,37</sup> also adjusted for occupational factors such as job role, company size, and workplace characteristics. The most common variable identified was age, which was adjusted for in statistical calculations in all but one study.<sup>30</sup> Two studies<sup>31,34</sup> make reference to the prevalence of precarious employment being higher in younger age groups, two studies<sup>29,32</sup> make reference to age having an effect on health, and one study<sup>36</sup> explicitly stated age as a confounding variable. The remaining studies did not have an open rationale for adjusting for age.

## DISCUSSION

One of the fundamental principles of public health is to address health

inequalities that persist, including those within the wider determinants of health – such as employment. This scoping review further examines three subpopulations (young individuals, migrant workers, females) that have been identified in the literature to be at an unequal exposure to precarious employment and explores the impact on health. We have structured the discussion to mainly focus on the recent literature featuring these three subpopulations. Finally, we appraise what the current literature is missing and suggest some direction(s) for future research.

### Gender differences

As previously commented upon in the 'Results' section, the majority of included studies ( $n = 12$ ) examined gender differences in health outcomes in relation to precarious employment exposure (Table 2). The research gap reported in 2007 has been somewhat filled a decade later.<sup>17</sup> Mental wellbeing was explored in seven studies,<sup>25–28,34–36</sup> self-rated general health in four studies,<sup>25,29–31</sup> and two studies explored mortality.<sup>37,38</sup> In the seven studies that examined mental wellbeing, four of these reported poorer mental health outcomes in both men and women employed in precarious employment.<sup>25–28</sup> Some studies reported up to and over a twofold increased risk of poorer mental health,<sup>26,28</sup> and this was observed in one study aligned to the employment precariousness, irrespective of contract type.<sup>28</sup> Higher educated men in fixed-term or atypical employment exhibited worse mental health outcomes than their equally educated female counterparts employed in these contract arrangements.<sup>26</sup> In two of three studies, it was observed that men in precarious employment were at greater risk of poorer mental health compared to women,<sup>34,35</sup> whereas one study demonstrated women at greater risk than men.<sup>36</sup> Furthermore, in men, risk of psychological distress was higher in those employed continuously in precarious employment,<sup>35</sup> but this did not increase the risk of new-onset depressive symptoms.<sup>36</sup>

Within the included literature, there were inconsistencies reported in terms of self-reported health. Self-reported health in males employed in precarious employment was worse compared to permanent employment in two studies,<sup>29,30</sup> but there were no differences reported in the other two studies.<sup>25,31</sup> In women, some studies observed poorer self-reported health in temporary workers that was four times higher compared to permanent workers,<sup>25,31</sup> although in the other studies there were no reported differences.<sup>29,30</sup> It was interesting that in the four studies that examined self-reported health, there were no consistent observations in both men and women reporting poorer self-reported health. The final health outcome that examined gender differences was mortality. Compared to their counterparts in permanent employment, men in temporary employment at baseline had higher all-cause mortality, in particular cardiovascular mortality (adjusted hazard ratio (HR)=3.56; 95% confidence interval (CI)=1.02–12.44) when followed up 13 years later.<sup>38</sup> These findings were mediated by pre-existing health conditions and lifestyle factors.<sup>38</sup> In a similar follow-up period, and using the same data source,<sup>37</sup> it was observed that premature mortality was far more pronounced in men (adjusted HR=2.23; 95% CI=1.42–3.51) that had worked in precarious employment than women (adjusted HR=1.11; 95% CI=0.56–2.20).

### Young individuals

We identified three studies<sup>26,29,32</sup> that met our inclusion criteria and examined the impact of precarious employment on young individuals (Table 3). Two of these studies<sup>26,32</sup> explored the mental health outcomes associated with precarious employment and the other study examined general health.<sup>29</sup> With regard to the quality of these studies, we had only similar minor concerns about loss to follow-up for the mental health outcomes,<sup>26,32</sup> but no such concerns for the study exploring self-reported health.<sup>29</sup> Overall, one of the cohort studies calculated the incidence rate ratio of experiencing poor mental health to be

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Table 2.

## Main findings for studies examining gender differences

Author, country	Statistical methods	Health measures	Findings	General health	Mental health	Mortality
Fiori et al., <sup>26</sup> Italy	Linear regression models	Mental Health inventory (derived from the SF-36)	-	-	Males who reported having the worst mental health were those in atypical employment ( $\beta = 2.763$ ), self-employed ( $\beta = 2.317$ ), and employed under a fixed-term contract ( $\beta = 1.684$ ). Among more educated men, those in a less secure position (Fixed-term: $B = 3.789$ ; Atypical: $B = 4.498$ ) had a statistically significant higher risk of poor mental health than men in permanent employment. Females who had a fixed-term contract had poorer mental health ( $\beta = 2.547$ ), among highly educated women those in fixed-term employment were at a greater risk of poor mental health ( $\beta = 2.547$ ).	-
Julià et al., <sup>28</sup> Spain	Poisson regression models/ adjusted prevalence rate ratios. Adjusted for age, social class, education status, place of birth, company tenure, and job insecurity.	Mental health inventory (derived from the SF-36)	-	-	Overall, temporary workers had poorer mental health than permanent workers. However, the association with poor mental health was unexpectedly stronger in permanent workers with high precariousness (aOR = 2.97, 95% CI = 2.25–3.92 in males, aOR = 2.50, 1.70–3.67 in females) than in temporary workers (aOR = 2.17, 95% CI = 1.59–2.96 in males, aOR = 1.81, 95% CI = 1.17–2.78 in females).	-
Kachi et al., <sup>35</sup> Japan	Cox proportional hazard ratio (HR) models	K-6 self-rated scale (6 questions, $\geq 14$ used as cut-off to define Serious Psychological Distress)	-	-	Exposure to precarious employment in males was associated with a higher risk of serious psychological distress (adjusted HR = 1.79; 95% CI = 1.28–2.51) and was more pronounced in males who were continually employed in precarious arrangements (adjusted HR = 2.32; 95% CI = 1.59–3.40). In females, there were no statistically significant observations between serious psychological distress and exposure to precarious employment (adjusted HR = 0.96; 95% CI = 0.72–1.29).	-
Khiat et al., <sup>38</sup> France	Cox survival regression/adjusted hazard ratios (HR)	Death (all-cause, non-violent causes, cardiovascular disease, cancer, violent causes)	-	-	-	In males, compared to permanent workers, temporary workers had higher all-cause mortality (adjusted HR = 2.21; 95% CI = 1.16–4.24), non-violent mortality (adjusted HR = 2.22; 95% CI = 1.12–4.40), in particular cardiovascular mortality (adjusted HR = 3.56; 95% CI = 1.02–12.44). There was no significant difference for all-cause mortality observed in females (adjusted HR = 1.28; 95% CI = 0.45–3.62).

(Continued)



Table 2. (Continued)

**Main findings for studies examining gender differences**

Author, country	Statistical methods	Health measures	Findings	General health	Mental health	Mortality
Kim et al., <sup>36</sup> South Korea	Multivariate logistic regression	Centers for Epidemiologic Studies Depression Scale (11-question version)	-	-	In both <i>males</i> and <i>females</i> , continual precarious employment showed no association with new-onset of depressive symptoms ( <i>Males</i> : aOR = 1.59; 95% CI = 0.90–2.81; <i>Females</i> : aOR = 1.50; 95% CI = 0.69–3.25). In <i>females</i> , new-onset depressive symptoms were higher in any employment transitions that included precarious employment (permanent-precarious: aOR = 2.88; 95% CI = 1.24–6.66; precarious-permanent: aOR = 2.57; 95% CI = 1.20–5.52). These observations were not statistically significant in <i>males</i> (permanent-precarious: aOR = 1.19; 95% CI = 0.57–2.50; precarious-permanent: aOR = 0.76; 95% CI = 0.39–1.46).	-
Minelli et al., <sup>29</sup> Italy	Fixed effects ordered logit model	SALUT (5-point Likert scale. Ranging from 1–'very poor' to 5–'excellent').	Self-reported health scores were lower in <i>male</i> temporary workers (compared to permanent employees) aged 15–40 years, but not <i>females</i> . <i>Male</i> first-job seekers were also observed to have lower self-reported health scores.	-	-	-
Niechammer et al., <sup>37</sup> France	Hazard ratios (adjusted for SES, age, lifestyle factors, work conditions, social support)	Premature mortality (death before the age of 70 years), all-cause mortality, total mortality.	-	-	-	In temporary workers, premature mortality was adjusted HR = 1.80 (95% CI = 1.24–2.63) times higher than in permanent employees. This observation was far more pronounced in <i>males</i> (adjusted HR = 2.23; 95% CI = 1.42–3.51) than <i>females</i> (adjusted HR = 1.11; 95% CI = 0.56–2.20).
Pirani and Salvini, <sup>31</sup> Italy	Marginal structural model (adjusted for age, marital status, area of residence, education, financial situation, occupation, pre-existing condition)	Poor self-rated health combined of 'very poor', 'poor' and 'fair' responses. (WHO suggested question 'How is your health in general?').	In <i>females</i> , compared to permanent employment, poor self-rated health greater in temporary contracts (aOR = 4.95; 95% CI = 2.10–11.69). This observation was present in transitions from permanent-temporary (aOR = 5.56; 95% CI = 1.86–16.61) and consistently temporary (aOR = 4.28; 95% CI = 1.83–10.02). In <i>males</i> , none of these observations were statistically significant. Poor SRH in temporary employment compared to permanent (aOR = 2.06; 95% CI = 0.76–5.57).	-	-	-

(Continued)

## Differences in the impact of precarious employment on health across population subgroups: a scoping review

Table 2. (Continued)

## Main findings for studies examining gender differences

Author, country	Statistical methods	Health measures	Findings	General health	Mental health	Mortality
Richardson et al., <sup>34</sup> Australia	Random effects panel model	Mental Health Inventory (derived from the SF-36).	-	-	This study found almost no evidence that flexible employment harms mental health. Among the employed, only <i>males</i> educated to diploma level employed either fixed-term full-time (coefficient: -2.479) or part-time (coefficient: -0.928) has lower mental health scores.	-
Samuelsson et al., <sup>30</sup> Sweden	Multiple linear regression	GHQ-six-item version.	One significant interaction was observed; gender moderated the association between temporary employment and poor SRH. Stratified analyses (by gender) indicated that temporary employment was significantly associated in <i>males</i> ( $\beta=0.11$ , $p<.05$ ) but not <i>females</i> ( $\beta=-0.05$ , NS).	-	-	-
Sidorchuk et al., <sup>27</sup> Sweden	Crude and adjusted odds ratios (aOR). Adjusted for socioeconomic position, disposable family income, and survey year.	GHQ-12. Below 3 good mental health, $\geq 3$ poor mental health	-	-	When compared to permanently employed counterparts, the odds of experiencing psychological distress was higher in <i>males</i> (aOR= 1.35; 95% CI= 1.15–1.59) than <i>females</i> (aOR= 1.17; 95% CI= 1.05–1.31).	-
Sousa et al., <sup>25</sup> Spain	Prevalences, crude and adjusted odds ratios (aOR)	Poor self-rated health combined of 'very poor', 'poor' and 'fair' responses. GHQ-12 (Mental Health). Below 3 good mental health, $\geq 3$ poor mental health	In <i>males</i> , poor self-rated health was not strongly influenced by contract arrangements. Compared to Spanish born, permanent workers, <i>females</i> at highest risks of poor self-rated health are foreign-born workers who have been in Spain >3 years with no employment contract (aOR= 4.63; 95% CI= 1.95–10.97) or temporary contract (aOR= 2.36; 95% CI= 1.13–4.91).	Compared to Spanish born, permanent workers, <i>male</i> foreign-born workers on temporary contracts who have lived in Spain for less than 3 years were at the highest risk of poor mental health (aOR= 1.96; 95% CI= 1.13–3.38). Compared to Spanish born, permanent workers, <i>females</i> at highest risks of poor mental health are foreign-born workers who have been in Spain >3 years with no employment contract (aOR= 1.93; 95% CI= 0.95–3.92).	-	

SF-36: Short Form-36 (SF-36) health questionnaire; B: unstandardised coefficient; aOR: adjusted odds ratio; CI: confidence interval; HR: hazard ratio; K6: shortened Kessler Psychological Distress scale; WHO: World Health Organization; SRH: self-rated health; GHQ: General Health Questionnaire;  $\beta$ : standardised beta values;  $\beta$ : socioeconomic status.

## Differences in the impact of precarious employment on health across population subgroups: a scoping review

Table 3.

Main findings for studies examining young individuals					
Author, Country	Statistical methods	Health measures	Findings		
			General health	Mental health	Mortality
Canivet et al., <sup>32</sup> Sweden	Data presented as percentages and age-adjusted incidence rate ratios (IRR)	General Health Questionnaire (GHQ-12). 'GHQ-caseness' defined as a scoring of 2 or higher.	–	An employment trajectory that included precarious employment, the IRR for poor mental health was 1.4 (95% CI = 1.1–2.0). The Population Attributable Fraction (PAR) for poor mental health was 18%.	–
Fiori et al., <sup>26</sup> Italy	Linear regression models	Mental Health Inventory (MHI). For ease of interpretation, the MHI was then transformed into a 0–100 scale using a transformation formula.	–	Those seeking their first job were at greater risk of experiencing poor mental health (Males: $B = 5.158$ ; Females: $B = 2.499$ ).	–
Minelli et al., <sup>29</sup> Italy	Fixed effects ordered logit model	SALUT (5-point Likert scale). Ranging from 1–'very poor' to 5–'excellent'.	Self-reported health (SRH) was lower in temporary workers aged 15–40 years. First-job seekers in this younger age bracket also reported lower SRH.	–	–

IRR: incidence rate ratios; GHQ: General Health Questionnaire; CI: confidence interval; PAR: population attributable fraction; MHI: Mental Health Inventory;  $B$ : unstandardised coefficient; SRH: self-reported health.

1.4 (95% CI = 1.1–2.0) for those individuals with any exposure to precarious working arrangements in their employment history.<sup>32</sup> Self-reported health was also found to be lower in young individuals employed in temporary employment compared to those in permanent employment.<sup>29</sup> Those seeking their first job were also at a greater risk of experiencing poorer general and mental health.<sup>26,29</sup> The observations concerning seeking first employment have important connotations especially when considering education levels.<sup>39</sup> Employment requiring higher levels of qualifications is often secure and protected, whereas employment opportunities with no such educational requirements has the tendency to be temporary and less regulated, that is,

precarious.<sup>3,39</sup> It was therefore interesting to observe that the more educated individuals who had fixed-term positions had poorer mental wellbeing.<sup>26</sup>

It should be acknowledged that five of the other studies included in this review<sup>25,28,31,33,36</sup> explored age as a demographic characteristic when presenting their results on the sample distribution of precarious employment. One of these studies demonstrated that temporary contracts were more prevalent in the younger age groups,<sup>31</sup> whereas another study identified that younger individuals even in permanent positions also experienced precarious employment.<sup>28</sup> None of these studies explored the health outcomes associated with precarious employment by age group. This clearly demonstrates that there

is existing and available data, yet to be utilised to examine the extent of health inequalities experienced by the younger demographic. In addition, the cohort study undertaken by Samuelsson et al.<sup>30</sup> followed up individuals from age 30 up to 42 years, although the analysis did not compare age groups, the findings still have relevance for the younger age groups.

### Migrant workers

We identified three studies that examined the health impacts on migrant workers (Table 4), all three of which focused on mental health outcomes,<sup>25,27,33</sup> with one study also exploring self-rated health.<sup>25</sup> There were no concerns about the quality of the cross-sectional studies,<sup>25,27</sup> with only minor concerns about loss to follow-up in the cohort study.<sup>33</sup> One of

## Differences in the impact of precarious employment on health across population subgroups: a scoping review

Table 4.

Main findings for studies examining migrant workers					
Author, Country	Statistical methods	Health measures	Findings		
			General health	Mental health	Mortality
Robert et al., <sup>33</sup> Spain	Crude and adjusted odds ratios (aOR)	GHQ-12 (Spanish language version). Below 3 good mental health, ≥3 poor mental health.	–	Increased risk of poor mental health (aOR) in employment with no contract (2.24; 95% CI=0.76–6.67), from employment to unemployment (3.62; 95% CI=1.64–7.96), decreased income (2.75; 95% CI=1.08–7.00), and continuous low income (2.73; 95% CI: 0.98–7.62).	–
Sidorchuk et al., <sup>27</sup> Sweden	Crude and adjusted odds ratios (aOR).	GHQ-12. Below 3 good mental health, ≥3 poor mental health. Outcome severity cut-off score of 7.	–	Increased risk of psychological distress in immigrants who are temporary employed (compared to permanently or self-employed). Crude: 1.86 (95% CI=1.57–2.20), aOR: 1.60 (95% CI=1.34–1.92). More apparent in refugees (aOR=1.71; 95% CI=1.37–2.15) than non-refugees (aOR=1.36; 95% CI=1.01–1.81).	–
Sousa et al., <sup>25</sup> Spain	Prevalences, crude and adjusted odds ratios (aOR)	Poor self-rated health combined of 'very poor', 'poor' and 'fair' responses. GHQ-12 (Mental Health). Below 3 good mental health, ≥3 poor mental health.	Compared to Spanish born, permanent workers, females at highest risks of poor self-rated health are foreign-born workers who have been in Spain >3 years with no employment contract (aOR=4.63; 95% CI=1.95–10.97) or temporary contract (aOR=2.36; 95% CI=1.13–4.91).	Compared to Spanish born, permanent workers, females at highest risks of poor mental health are foreign-born workers who have been in Spain >3 years with no employment contract (aOR=1.93; 95% CI=0.95–3.92). Compared to Spanish born, permanent workers, male foreign-born workers on temporary contracts who have lived in Spain for less than 3 years were at the highest risk of poor mental health (aOR=1.96; 95% CI=1.13–3.38).	–

aOR: adjusted odds ratio; GHQ: General Health Questionnaire; CI: confidence interval.

the major consistencies, and therefore strengths, within these studies is that all of them assessed mental wellbeing using the 12-item version of the GHQ-12 and used the same 'caseness' threshold of 3 to determine poor mental health. There was a greater risk of poor mental wellbeing in migrant workers in precarious employment (compared to migrant workers in permanent employment) ranging from aOR=1.60 (95% CI: 1.34–1.92)<sup>27</sup> up to aOR=2.24 (95% CI: 0.76–6.67).<sup>33</sup> Compared to native men in permanent employment,

these risks were even greater in those with refugee status (men: aOR=2.39 (95% CI: 1.32–4.30); women: aOR=3.71 (95% CI: 2.31–5.95)).<sup>27</sup> Those who experienced components associated with precarious employment such as job loss (aOR=3.62 (95% CI: 1.64–7.96)) and decreased income (aOR=2.75 (95% CI: 1.08–7.00)) were found to be at even greater risk of poor mental health.<sup>33</sup> In addition, working without a contract and being resident in a foreign country for less than 3 years also increased the risk of both poor mental and general health.<sup>25</sup>

Notably, one study observed that female migrant workers in non-permanent employment demonstrated poorer self-reported health, but men did not.<sup>25</sup>

### Gaps in literature and next steps

Although being disproportionately at risk of exposure to precarious employment, there are limited studies that explore the health implications of precarious employment on young individuals. Our review echoes a recent scoping study on this demographic group, which explored health outcomes experienced through both unemployment

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and precarious employment and proposed the need for further longitudinal research with a focus on gender outcomes and third factor (e.g. personality traits, job, and family histories) considerations.<sup>15</sup> Now, more than ever, with the probable economic and employment considerations which result from the global Covid-19 pandemic, it is important this new youthful generation, particularly vulnerable in a likely unstable labour market,<sup>15</sup> do not experience the same enduring detrimental consequences to mental wellbeing as their predecessors.<sup>3,40</sup> Despite inequities that persist with exposure to precarious employment in migrant workers, there were only a small number of studies included in our review. We acknowledge that some qualitative research has been undertaken in this subpopulation to explore their experiences,<sup>41</sup> so understanding in the migrant worker group may not be as limited as the knowledge surrounding young individuals.

Only one of the included studies<sup>28</sup> explicitly calculated employment precariousness using the Employment Precariousness Scale (EPRES), all other studies defined precarious employment as either temporary, fixed-term, or atypical contract arrangements which is a limitation of the evidence base previously reported by others.<sup>5</sup> The literature also contains inconsistencies when grouping employment and contract types together to create reference categories. Another inconsistency in approach was the inclusion or exclusion of those who are in self-employment, since the EPRES explicitly excludes self-employment from the calculation.<sup>10,11</sup>

It should also be acknowledged that some support structures such as a stable relationship,<sup>35,42</sup> perceived job control,<sup>43</sup> managerial support,<sup>44</sup> or even the personal choice of working in precarious arrangements<sup>45</sup> can somewhat negate (or buffer) some of the adverse health impacts associated with precarious employment. Marital status or living arrangements were adjusted for in five studies;<sup>26,31,34–36</sup> however, none of the other aforementioned buffering factors were fully evident within the included literature.

In terms of global health implications and research opportunities, the included

studies all took place in developed countries. It was surprising that no studies undertaken in the United States, Canada, United Kingdom, or Germany (four of the G7 countries) met our inclusion criteria. Nevertheless, this highlights a lack of understanding to both the extent of precarious employment in low- and middle-income countries (LMICs) and the associated impacts on population health in these countries. There was also a reliance within the current literature on self-reported measures for health. One disadvantage to this approach is that there can be discrepancies between self-reported health and biomarker data, that is, lower perceived feelings of general health do not necessarily result in worse health biomarkers.<sup>46</sup> The recent advancements in data linkage between health and administrative records presents an opportunity to reduce the reliance of self-reported measures and use medical data to examine the impact of precarious employment on health outcomes.

There are a number of limitations to state in our review. We decided not to include workplace injuries as a health outcome in this review. We acknowledge that a body of evidence exists to suggest that precarious employment is associated with hazardous working conditions. However, a systematic review on precarious employment and occupational accidents and injuries has recently been undertaken<sup>47</sup> and we felt including injuries as a health outcome in our review would not add to this recent publication. Only peer-reviewed published literature in English was included in our review; therefore, grey literature and research published in other languages were not considered, potentially excluding some current evidence from our overview.

### CONCLUSION

Our review further explores an emerging social determinant of health;<sup>6</sup> this time with a scoping focus on the inequalities presented in the current, good quality literature. We examined the impacts of precarious employment on health in three subpopulation differences: young individuals, migrant workers, and gender differences. We found an abundance of literature exploring gender differences in health; there were clear inconsistencies in

relation to self-reported health, and males with exposure to precarious employment were more at risk of mortality, including premature mortality. On the whole, poorer mental wellbeing was associated with precarious employment in both males and females, although continual exposure to precarious employment appeared to be more detrimental to males. Unfortunately, there was limited evidence examining the health impacts on young individuals and migrant workers, and it is these two subpopulations that are exposed to precarious employment most often. More research needs to be undertaken to fully understand the implications of such contract arrangements on both short- and long-term health for young individuals and migrant workers, particularly to compare pre- and post-Covid pandemic impact. Furthermore, there is a need for drivers of health equity, particularly policy coherence, to consider the policy and legislative impact of precarious employment trends, particularly on the health and wellbeing of vulnerable subgroups of the population<sup>3</sup> to ensure that they are not being left behind.

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# BMJ Open Programme and policy perspectives towards a tobacco-free generation in India: findings from a qualitative study

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## ABSTRACT

**Objective** This study explored multistakeholder perspectives on existing adolescent-specific tobacco control policies and programmes, to advance India's transition towards a tobacco-free generation.

**Design** Qualitative semi-structured interviews.

**Setting** Interviews were conducted with officials involved in tobacco control at the national (India), state (Karnataka), district (Udupi) and village level. Interviews were audio recorded, transcribed verbatim and analysed thematically.

**Participants** Thirty-eight individuals representing national (n=9), state (n=9), district (n=14) and village (n=6) levels, participated.

**Results** The study findings highlighted the need to strengthen and amend the existing Tobacco Control Law (2003) provisions, particularly in the vicinity of schools (Sections 6a and 6b). Increasing the minimum legal age to buy tobacco from 18 to 21 years, developing an 'application' for 'compliance and monitoring indicators' in Tobacco-Free Educational Institution guidelines were proposed. Policies to address smokeless tobacco use, stricter enforcement including regular monitoring of existing programmes, and robust evaluation of policies was underscored. Engaging adolescents to co-create interventions was advocated, along with integrating national tobacco control programmes into existing school and adolescent health programmes, using both an intersectoral and whole-societal approach to prevent tobacco use, were recommended. Finally, stakeholders mentioned that when drafting and implementing a comprehensive national tobacco control policy, there is a need to adopt a vision striving toward a tobacco-free generation.

**Conclusion** Strengthening and developing tobacco control programmes and policies are warranted which are monitored and evaluated rigorously, and where adolescents should be involved, accordingly.

## BACKGROUND

Tobacco use is a leading risk factor associated with several diseases, premature death and disability. It is a major threat to developing and low-income/middle-income countries such as India, where tobacco use results in 1.35 million deaths, annually.<sup>1,2</sup> Furthermore, of all deaths related to non-communicable

## STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This study captures perspectives on existing tobacco control policies in India, from a diverse range of stakeholders representing different levels of governance (national/state/district/village).
- ⇒ Perspectives were captured on existing tobacco control policies and programmes, barriers and facilitators to their successful implementation and suggested recommendations for strengthening existing and developing new policies to achieve the ultimate goal of a tobacco-free generation for India as well as replicate such models globally.
- ⇒ Despite the fact that the interviewees for the in-depth interviews were not randomly selected, our study findings are still significant and transferable.

diseases in India, in 2019, approximately 1.08 million deaths (17.7%) were due to tobacco use.<sup>3</sup> The prevalence of tobacco use among adults in India has declined from 34% to 28% between 2010 (Global Adult Tobacco Survey (GATS-1)<sup>4</sup> and 2017 (GATS-2)<sup>5</sup> and among school-going students aged 13–15 years from 16.9% (Global Youth Tobacco Survey (GYTS-1, 2003)<sup>6</sup> to 8.5% (GYTS-4, 2019).<sup>7</sup> The majority of adult tobacco users initiate use during adolescence,<sup>8</sup> often leading to lifelong use, with low quit rates.<sup>9</sup> Therefore, prevention of tobacco uptake among children and adolescents is crucial to reducing the harms caused by tobacco use. There are many tobacco control programmes and policies, but the need for age-specific policies has gathered prominence in recent decades. Adolescent-specific policies are warranted, especially, preventing uptake in the first place.<sup>10</sup>

The Government of India (GoI) has implemented various policies and programmes to prevent tobacco uptake among children and adolescents. Section 6a of the Cigarettes and Other Tobacco Products (Prohibition of Advertisement and Regulation of Trade

and Commerce, Production, Supply and Distribution) Act (COTPA) 2003,<sup>11</sup> stipulates the prohibition of the sale of tobacco products to and by minors; and Section 6b, prohibits the sale of tobacco products within the surrounding 100 yards of educational institutions.<sup>11</sup> As part of the 'National Tobacco Control Programme' (NTCP), India also launched the School Programme across public and private schools, to equip young people with the knowledge and appropriate skills to make informed decisions related to tobacco consumption and build understanding on the consequences of tobacco use.<sup>12</sup> To reinforce such efforts, the Ministry of Health and Family Welfare (MoHFW)-GoI also introduced 'Tobacco-Free Educational Institution' (ToFEI) guidelines,<sup>13</sup> for all education establishments, across India, to generate awareness about the harmful and long-term effects of tobacco use and to create healthy tobacco-free educational institutes.

Despite these efforts, the implementation of tobacco control policies continues to be a challenge.<sup>14</sup> The evidence is mixed on whether investing in youth and adolescent tobacco control and prevention efforts is effective.<sup>15</sup> A growing focus is on 'anti-tobacco' interest groups and their influence on policy implementation and success.<sup>16</sup> Multiple partnerships have been found to be beneficial in tobacco control policy implementation at various levels.<sup>17 18</sup> Thus, considering the perspectives of various stakeholders for formulating tobacco control policies might be the way ahead. Perspectives from multiple stakeholders increases the range and quantity of information for researchers and thus increases the likelihood of actions being developed and implemented.<sup>19</sup>

This study explored the views of a diverse range of stakeholders (including policymakers, policy implementers, representatives from civil society, implementation agencies and other stakeholders) on India's existing tobacco control policies and programmes focusing on adolescents, barriers to and facilitators for their successful implementation and suggested recommendations for the future.

## METHODS

### Design

Qualitative, one-to-one, semi-structured interviews were conducted with key officials at the national (India), state (Karnataka), district (Udupi) and village level.

### Patient and public involvement

Patients or the public were not involved in the design, conduct, reporting or dissemination plans of our research.

### Recruitment and sampling

A purposive sampling strategy was developed<sup>19 20</sup> where a list of 51 eligible individuals was drafted by members of the research team (MA, SB and MMK), based on professional networks and level of engagement with tobacco control programmes, at different levels of governance. The interviewees varied in terms of their roles, responsibilities and

seniority, to ensure that a wide range of perspectives were captured. Potential interviewees were approached by SB and RB via email and telephone. A study information sheet and consent form were sent prior to completing interviews, and an interview was arranged at a time convenient for each individual.

### Data collection and procedure

A semi-structured interview guide was developed to explore interviewees' views on existing adolescent-specific tobacco control policies and programmes in India, barriers and facilitators to successful implementation, as well as recommendations for their successful implementation and strengthening, to advance India's transition towards a tobacco-free generation. The interview guide was developed by SB, MB, with inputs from MA, MMK and VG, and was based on the School Programme component delivered as part of NTCP,<sup>12</sup> ToFEI guidelines by MoHFW,<sup>13</sup> provisions of the Indian Tobacco Control Act (2003),<sup>11</sup> that specifically addressed the prevention of tobacco uptake and use among children and adolescents (online supplemental table 1).

Interviews were conducted between July 2019 and September 2021, in English by trained qualitative researchers. National and state-level stakeholder interviews were moderated by SB, while district and village level by MMK and RB. Due to the COVID-19 mitigation measures in India (eg, travel restrictions), national and state-level interviews were conducted virtually using Zoom (during December 2020 to September 2021), while district and village level interviews were conducted in-person (from July 2019 to March 2020). The interviewees were asked to review and sign a consent form prior to interview (verbal consent was sought for virtual interviews). The consent process covered permission for data collection, audio recording of interviews, data to be used in research publications and dissemination while maintaining interviewee confidentiality and anonymity.

### Data analysis

Interviews were transcribed verbatim by members of the research team. Identifiable data were anonymised and double-checked for accuracy by senior members of the research team. Transcripts were analysed by SB, NT and MB using thematic analysis<sup>21</sup> where both inductive and deductive approaches<sup>22</sup> were adopted. To ensure the validity of interpretations,<sup>23</sup> each individual familiarised themselves with the data separately which led to the identification of initial codes. Further readings resulted in the development of more substantive themes and subthemes. Following this, a series of virtual calls were organised between SB, NT and MB to discuss preliminary themes which led to a more definitive thematic framework, which was agreed and then applied to the remaining data (by NT). NVivo 12.0 was used to facilitate the analysis process and subsequent synthesis and reporting.



**Table 1** Demographic characteristics of the study interviewees (N=38)

	N (%)
Sex	
Male	26 (68.4)
Female	12 (31.6)
Geographical representation	
National	9 (23.7)
State	9 (23.7)
District	14 (36.8)
Village level	6 (15.8)
Years of working experience in tobacco control	
0–5 years	9 (23.7)
6–10 years	7 (18.4)
>10 years	10 (26.3)
Not available	12 (31.6)
Type of organisation	
Government	26 (68.4)
Civil society representatives	11 (29)
Development agency	1 (2.6)

## RESULTS

Thirty-eight interviews were conducted with: 9 national-level, 9 state-level (Bengaluru, Karnataka), 14 district (Udupi) level and 6 village-level stakeholders (table 1). Interviewees included officials from the NTCP, members of the tobacco control committee (national, state and district level), representatives from civil society organisations working in tobacco control, health, education, agriculture, food and civil supplies, police, parliamentary affairs, district administration, rural development and Panchayati Raj (a system of local self-government of villages in rural India). Interviews averaged 44 min (range 20–111 min).

### Thematic analysis

Four themes were generated: (1) Views on existing tobacco control policies and programmes focusing on adolescents in India; (2) Barriers and facilitators to successful implementation; (3) Recommendations for successful implementation; and (4) Strengthening adolescent-specific tobacco control policies and programmes to advance India's transition towards a tobacco-free generation.

### Views on existing tobacco control policy and programmes focusing on adolescents in India

Interviewees reported many tobacco control programmes and policies to prevent tobacco uptake among adolescents. They believed school-based programmes or interventions to have an important role in preventing adolescents from using tobacco. Most of the interviewees spoke about the 'School Health Programme', which forms part of NTCP, and a few also mentioned smaller regional or local

initiatives such as, the 'Yellow line campaign' (wherein, two yellow lines are painted 100 yards away from the boundary wall of an education institute demarking a 'No Tobacco Zone'); the 'Rose Campaign' (where a rose flower was given to petty shop owners selling tobacco and were made aware of its consequences and asked to display boards with tobacco warnings); the 'National Population Education Project' (creating awareness or helping adolescents understand the impact of using tobacco through several activities, such as poster competitions, memes, folk dance, skits, role play, mono acting) and also other community-based activities with the involvement of local leaders and the formation of a 'Taluka level coordination committee' (a group of several villages counted together for administrative purposes), for controlling tobacco in the community.

As part of the NTCP, the interviewees mentioned the ongoing sensitisation activities (sessions/talks/audio-visual clips) school children were exposed to, as well as the formation of anti-tobacco school committees, making an anti-tobacco pledge in school assembly, the organisation of anti-tobacco themed competitions like drawing, posters, painting, quiz competitions and relay-races. Some spoke of annual competitions to formulate an anti-tobacco message and role-play activities, along with cultural-day programmes in schools, to generate awareness of tobacco, among both students and parents. A representative from the State Education Department mentioned that many school teachers are also invited to be a part of government-organised sensitisation training, which aims to create awareness about the consequences of using tobacco for school children, where manuals were reportedly provided to school authorities, to aid the process.

We have received a manual, wherein information about cigarette content, and activities to be taken by the students to not fall into the trap is provided. There are many pictures in that, wherein it is displayed about the effects of usage of tobacco, and many more things are there in the manual. There are several activities and content that create awareness among students and we have already passed this to school authorities.

Many interviewees also discussed the ToFEI guidelines developed by the MoHFW. A national-level non-governmental organisation (NGO) representative highlighted that the most important indicator in ToFEI, deals with the implementation of section 6b of COTPA around the prohibition of the sale of tobacco near educational institutes:

One of the great outcomes that have come out of this ToFEI programme is section 6b of COTPA which prohibits any shop selling tobacco within 100 yards of any educational institute, right? And the industry makes sure that the shops are there. One of the components in these guidelines makes us report the number of tobacco shops which are around these schools.

### Barriers and facilitators to successful implementation of tobacco control programmes and policies

Most interviewees reported weak monitoring and enforcement of 'NTCP' and 'ToFEI guidelines' as the primary barrier to their successful implementation. A national level civil society representative stated that, 'there is no mechanism to monitor how many schools are tobacco-free in the state'. Another interviewee mentioned that the guidelines were limited in terms of their reach, 'The guidelines are not reaching upto where it has to, like if we talk about educational institutions. The Principals, the administrative authorities of these educational institutions seem to be unaware and they are unaware because nobody has reached out to them'. Some also referred to a lack of dedicated staff to carry out programme activities and budget as barriers to programme implementation. A national-level representative said, 'There are 75 districts, there is staff only in 26 districts, 26 districts do proper reporting and monitoring but the remaining districts are not able to do because there are no staff specific to our department'.

Some even mentioned the lack of subnational level representation during the policy development process as a barrier. Many stated a lack of awareness about the ongoing nature of these programmes, the Tobacco Control Act, and its provisions among members of enforcement agencies (organisations that are responsible for programme implementation education, police department, etc), were barriers to successful implementation of programmes. The COVID-19 pandemic was also mentioned by some as a barrier, because of the way it has overwhelmed many systems, especially within health and education, due to schools being closed for more than one academic year making tobacco control trivial.

Many interviewees proposed a bottom-up approach to facilitate proper implementation of existing programmes and policies. Some suggested prioritising the NTCP programme at all levels, especially subnationally, along with amalgamating school-based programmes under one umbrella, to facilitate better implementation of the NTCP. Some even mentioned implementing programmes (like NTCP and ToFEI guidelines) in coordination with other ministries, especially the police and education departments, for better coverage and enforcement. A national representative proposed a partnership between the Ministries of Health and Education to facilitate implementation of the ToFEI guidelines. Some representatives also mentioned that tobacco control needs to be incorporated and discussed in state and district-level developmental meetings. A state-level government representative said, 'District level Coordination Committee' meeting would be a very good platform where such issues can be highlighted and brought to notice of the deputy commissioner himself and when he pitches in.'

### Recommendations for successful implementation of tobacco control policies and programmes

#### Awareness generation and capacity building of enforcement agencies

While talking about the lessons and recommendations for strengthening adolescent-specific tobacco control efforts, most interviewees underlined the need to continuously educate adolescents about the consequences of using tobacco and how the tobacco industry uses deceptive tactics to entice them to take up their products. Using explicit examples, such as the techniques used by the tobacco industry were highlighted. More use of IEC (Information, Education and Communication) material, videos, short films and awareness campaigns, were suggested, along with the use of social media platforms (*Facebook, Twitter and WhatsApp*), due to their popularity among the younger generation. Many stressed the need for targeted sensitisation programmes for enforcement agencies on the importance of enforcing tobacco control laws.

Interviewees believed school-based interventions to be an important way to prevent adolescents from using tobacco. A state representative said to 'Take up important aspects of tobacco education into the curriculum of students wherein they are taught actively that, these are habits that are detrimentally harmful, and the industry is going to try and fool them and to look for industry interference'. Some interviewees also suggested co-creating adolescent-driven projects or interventions<sup>24</sup> engaging them in creating awareness among their peers, where an example from a school-based intervention delivered in Delhi schools was referred to:

The MYTRI trial, "if you see this element of peer activism in terms of interventions. So, if you do school-based interventions which are actively involving youth, as a change maker or as advocates, those interventions are more effective".

#### Strengthening the enforcement and monitoring of existing tobacco control policies and programmes

A state civil society representative suggested the education department needed to develop a monitoring tool to ensure compliance with ToFEI guidelines.

The educational department has to come up with a monitoring tool to assess the level of compliance with ToFEI. Practically someone from the education department has to physically verify the compliance. The school may upload the photographs but the physical verification by the concerned officers of the educational department and sharing the monthly progress report with the key stakeholders is more helpful to understand the level of compliance.

A national-level interviewee pointed out that the ToFEI guidelines need to be implemented properly, especially in village schools, where teachers must first be oriented, and better collaboration between ministries needs to be

addressed. In rural areas, integrating ToFEI guidelines in 'Aadarsh gaon Yojana' (Model village, Rural Development Model)<sup>25</sup> which focuses on village development and includes social, cultural development and social mobilisation of the village community; or Clean India Mission (Swachh Bharat Abhiyan)<sup>26</sup> a country-wide campaign initiated by the GoI to eliminate open defecation and improve solid waste management, was suggested.

To reduce and prevent tobacco use among youth, most interviewees emphasised establishing a comprehensive enforcement mechanism for implementing the COTPA Act, in the vicinity of educational institutions. Many even stated that specific amendments to COTPA-2003, especially surrounding educational institutes, such as increasing penalties/fines, were needed. The need for strengthening implementation of 6a and 6b of COTPA-2003 was highlighted by a state level civil society representative, 'So we have COTPA section 6a, and 6b provision. It says tobacco cannot be sold within 100 yards of any educational institution, so if you implement this particular section 100% in any state, any geographical area, then no chance of accessibility or availability of tobacco products'. Including section 6b in the 'regular checklist' for the school's inspector, along with strict enforcement in and around schools, was also advocated.

The significance of robust regular monitoring at every level was underscored by interviewees. All tobacco-related programmes, particularly those in schools, must be monitored by the government. The school's involvement in monitoring was considered critical. An official from the health department said 'we conduct a programme in one school and go back to that school after 4 years. So there need for proper monitoring of every school. So, there are 3000–4000 schools in every district. Covering all schools at such large scales can only be done through district human resources'. Similarly, many interviewees also suggested engaging civil societies, student self-help groups (like Bharat Scouts, National Cadet Corps), and police functionaries for monitoring and enforcement, to maximise effectiveness and increase programme accessibility.

#### Multisectoral and multistakeholder engagement

All interviewees commented on the successful implementation of any programme being dependent on having effective and efficient intersectoral collaborations, from national to grassroot levels (Panchayati Raj Institutions at the village level). The active involvement of all stakeholders, including health, non-health and NGOs, to safeguard adolescents from tobacco was also highlighted, 'we need to wage a battle. Finance, human resources, NGOs, policy, intersectoral collaboration not just within the health sector but with other departments also'. Many interviewees suggested integrating the NTCP into existing health and adolescent health programmes like the Ayushman Bharat Scheme,<sup>27</sup> National Adolescent Health Programme (Rashtriya Kishor Swasthya Karyakram)<sup>28</sup> and, National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke.<sup>29</sup>

We have a national tobacco control programme, we have a district cancer control programme, we have oral health programme, multiple tobacco control programmes which are being implemented. We have district tobacco control programme. There are multiple overlapping issues with each of these programmes, there has to be coordinated way and mechanism in which this could be implemented at the ground level and there has to be consistency in the way in which it has to be implemented.

#### Regular impact evaluation

Interviewees underscored the importance of routine programme and policy evaluation, particularly when considering the evolving nature of tobacco industry tactics to target adolescents. Research studies could help in identifying the loopholes or lacunae of the ongoing programmes by providing evidence and encouraging them to take corrective actions to improve them. It was stated that there is a need to identify opportunities and weaknesses in the context of regional, state and district variations, and thus, a multipronged approach should be developed accordingly, 'We need to calibrate intervention, and policies as per the development of industry and science and we regularly need to undertake impact evaluation studies to understand what are the gaps and what we have achieved'.

#### Strengthening adolescent-specific tobacco control policies and programmes to advance India's transition towards a tobacco-free generation

##### Development of new tobacco-free generation-centric policies

Many interviewees highlighted the need for new and achievable policies which focus on realising a tobacco-free generation. Considering the magnitude of smokeless tobacco use in India, many interviewees suggested, shift in focus of policymaking, from only smoking to both smoking and smokeless tobacco. Many even suggested increasing the minimum legal age to buy tobacco from 18 to 21 years. Vendor licensing was also identified as a key strategy to reduce accessibility to tobacco. A stakeholder from the state said, 'What happens when a child goes to buy chocolate or cakes and sees lots of tobacco products also...so there is a chance he may buy tobacco products also. Because everything is sold in one shop so there is a risk of a small child getting access to a tobacco shop. So here, by vendor licensing, what we are doing is, we are preventing accessibility of a child getting tobacco'.

Interviewees also spoke about developing policies or regulations to prohibit tobacco advertising, promotion and sale on 'Over The Top' (OTT) platforms. These are needed to protect minors from all direct and indirect methods (surrogate promotion by big tobacco) of promotion and sales on OTT platforms. E-cigarette sales on online platforms was referred to as an example of how compliance with the Prohibition of Electronic Cigarettes (Production, Manufacture, Import, Export, Transport, Sale, Distribution, Storage and Advertisement) Act,

2019 in the country is weak.<sup>30</sup> The interviewees stressed the need for strict monitoring of regulations on OTT platforms.

## DISCUSSION

The study emphasised the need for educating adolescents, communities, teachers and enforcement agencies on the consequences of tobacco use, tobacco control laws and the tobacco industry's deceptive tactics to target young people. For preventing tobacco use among adolescents, our study demonstrates the need to formulate policy around realising a tobacco-free generation, engaging adolescents meaningfully, co-creation of adolescent-specific tobacco control interventions, strengthening and amending COTPA provisions surrounding educational institutions, improving multisectoral and multi-stakeholder engagement, adopting the whole-societal approach, policies prioritising smokeless tobacco control and future research for identifying the loopholes or lacunae of the ongoing programmes. The importance of having robust monitoring and evaluation mechanisms was underscored, to ensure the most effective interventions and policies are in place.

The introduction of COTPA<sup>11</sup> and ToFEI guidelines<sup>13</sup> were considered prime steps towards tobacco control among adolescents. But even after years since these have been implemented, awareness and compliance remain a major concern, especially in rural settings and among enforcement agencies.<sup>31–35</sup> The study highlights a need to increase awareness among adolescents, teachers, community members and law enforcement agencies, which is supported by previous research.<sup>36–38</sup> Evidence from Maharashtra (India) showcased the positive effects of sensitisation efforts with police on enforcement of COTPA with an increased collection of 'challans' (fines)<sup>39</sup> and action against shops violating section 6b of COTPA.<sup>38</sup>

The need to develop adolescent-driven programmes to meaningfully engage adolescents, wherein they serve as ambassadors and be involved in creating awareness among their peers, their families and the community about tobacco use, was repeatedly emphasised in our findings. Many successful youth driven tobacco-based initiatives<sup>40–42</sup> have observed favourable results in terms of policy development,<sup>43</sup> sensitisation and reduced current tobacco use among youth.<sup>44</sup> A campaign engaging National Service Scheme (NSS) volunteers from 540 colleges in Mumbai resulted in improving awareness of tobacco control issues among 176 000 students,<sup>45</sup> and the use of NSS volunteers<sup>46</sup> was also suggested in our study to support tobacco control initiatives.

This study underscored the importance of using social media to promote tobacco control messages and restricting tobacco industry marketing on social media, due to its widespread use among youth.<sup>47</sup> Existing evidence supports the use of social media for tobacco control.<sup>48–52</sup> For example, a recent social media campaign sought to educate high school students on e-cigarettes

led to greater knowledge and beliefs about the harmful effects of e-cigarette use, suggesting social media as a promising tool for tobacco education, among young people.<sup>53</sup> Another study also demonstrated the use of digital media to empower adolescents in smoking prevention.<sup>54</sup> The need for extending the Tobacco Advertising, Promotion and Sponsorship (TAPS) ban to cover OTT platforms was underscored in our study. There is ample evidence worldwide showcasing the use (direct and indirect) of social networking sites for TAPS specifically targeting youth.<sup>55–58</sup> By using social media influencers, tobacco giants have found a way to circumvent policy guidelines.<sup>59</sup> Singapore passed laws on cyber surveillance and social media monitoring to counter the tobacco menace<sup>60</sup> and has also penalised and taken legal action on the TAPS violation.<sup>61</sup> A comprehensive ban on TAPS to ensure online streaming platforms are compliant with COTPA, is crucial for India to protect children from exposure to tobacco products displayed on the OTT platforms. Our study also recognises the need to amend existing policies and development of new policies from tobacco control and prevention to 'Tobacco-Free future Generation' or 'Tobacco Endgame', to make the next generation 'tobacco-free'. Several countries like Scotland,<sup>62</sup> Singapore<sup>63</sup> New Zealand,<sup>64</sup> Finland<sup>65</sup> and others are striving towards a tobacco-free goal. A study weighing up the impact of New Zealand's Tobacco-Free Generation policy found that the implementation of Tobacco Free Generation results in a substantial decrease in smoking prevalence.<sup>66</sup> India also needs to undertake strategic steps towards a tobacco-free generation by coordinating ongoing efforts of implementing ToFEI guidelines and global youth campaigns like NMT21C (No More Tobacco in the 21st Century).<sup>67</sup>

India should also consider making policy changes in the minimum legal age to buy tobacco, raising it from 18 to 21 years, as suggested by the stakeholders in our study. The evidence shows a high percentage of smokeless (75%) and smoking (77%) tobacco users in India initiate use before or up to the age of 21 years.<sup>68</sup> This is also supported by the scientific evidence that the brain continues to develop until about the age of 25 years. During this time period, brain growth is not complete and susceptibility to the damaging effects of tobacco smoke may be enhanced.<sup>69–70</sup> The probability that an adolescent will remain tobacco-free for the rest of his/her life is higher. The effectiveness of this approach can be seen in California where 'Tobacco 21' was passed in 2016 and this law has led to a decrease in the illegal sale of tobacco<sup>71–72</sup> and a decline in cigarette smoking in high school students.<sup>73</sup>

India also faces the dual challenge of dealing with tobacco smoking and smokeless tobacco, especially in rural areas where the prevalence of smokeless tobacco use is much higher.<sup>74</sup> Additionally most smokeless tobacco users are dual users<sup>75</sup> (who use both smokeless and smoking tobacco). Furthermore, current tobacco laws in the country are oriented towards smoking tobacco.

Hence, the need for the development of new policies to cater for smokeless tobacco users was also emphasised in both our and previous studies.<sup>76</sup> Vendor licensing as recommended in our study can help in reducing the vendor density, especially near schools,<sup>77</sup> and lower the odds of cigarette use initiation in adolescents.<sup>78</sup>

Findings from our study prioritises a need to strengthen the school health component which forms part of the ongoing NTCP, as school settings are deemed best for tobacco use prevention and addiction for children, school staff and families. Families have an enormous influence on a child's tobacco use behaviour<sup>79 80</sup> and this has also been reported in our study. Thus, parents, particularly in villages, need to be sensitised and should be involved in school-based tobacco-free efforts, to reduce tobacco exposure at home.

In terms of stricter implementation, our findings also highlight COTPA section 6b as the most important indicator for tobacco control among adolescents. In line with our findings, evidence largely supports the stricter implementation of section 6b of COTPA decreased tobacco use in adolescents<sup>81</sup> and vice versa (increased tobacco use by adolescents to proximity and density of retail outlets near schools).<sup>82</sup> The ToFEI guidelines emphasised the Self-Evaluation Scorecard for Tobacco-Free Educational Institutions and this is well aligned with our study findings on the regular evaluation of these guidelines.<sup>13</sup> With the widespread digital infrastructure in the country, compliance and monitoring of the indicators of ToFEI guidelines could benefit from the use of mobile application-based systems as suggested by stakeholders in our study. Similar application-based solutions have been implemented in several Indian states<sup>83</sup> and globally<sup>84 85</sup> and has been reported to improve awareness and surveillance in and around schools.

Our study interviewees emphasised that improved enforcement and implementation require collaborative multisectoral partnerships, which include schools, parents, officials at all levels (national, state and district), local representatives, civil society and government health and non-health departments. The multistakeholder partnerships have been observed to be beneficial in reducing tobacco use in many parts of the world.<sup>17 86 87</sup> For instance, in New Zealand almost all educational institutes that have declared themselves 100% tobacco-free reported collaboration with external providers.<sup>88</sup>

Despite the novel findings presented in the paper, a few study limitations are noted. We have captured the perspectives of a diverse range of stakeholders representing different levels of governance (at national, state, district and village level) other than adolescents, thus the beneficiary perspective (adolescents) on tobacco control policies is missing. Sampling was one of the limitations of our study, as the interviewees for the in-depth interviews were purposely selected. Nevertheless, we had a fairly balanced response in terms of stakeholders from different levels of governance and years of experience in tobacco control making our study

findings transferable and significant. Additionally, the lack of comparison of study findings to a framework can be looked at as a limitation that can be explored in future research.

## Conclusion

This study provides recommendations for strengthening the enforcement of existing, and developing new tobacco control programmes and policies focusing on adolescents to advance India towards the ultimate goal of a tobacco-free future generation and replicate such models globally.

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**Contributors** MA, JB, SB, MB and MMK developed the research questions and study methodology. SB and MB developed an interview guide and MA, MMK and VGK provided inputs to the interview guide. The list of interviewees was developed by MA, SB and MMK. SB, MMK and RB coordinated and conducted the interviews. Data was coded and thematically analysed by SB, MB and NT. SB, MB and NT drafted the manuscript. MA, JB, MMK, VGK, RB and IB critically reviewed the manuscript. All authors are responsible for the overall content as guarantors.

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**Data availability statement** Data are available upon reasonable request. Data are available on reasonable request. As per our institutional data sharing policy, prior approval is required from the Research Management Committee (RMC) and the principal investigator (PI) of the study. After Committee's approval of the request, de-identified data can only be shared upon request.

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