

Stephen Donnelly, Minister for Health:

I'm delighted to welcome you all to this Vaccine Advocate Forum. Earlier this year, some experts were warning that it could be years before a vaccine was ready for COVID-19, and they were providing this view, based on just how long other vaccines in history have taken to develop. But thanks to what might be the biggest global scientific collaboration in history, we're now talking about beginning to vaccinate people in Ireland very, very shortly. When you take into account that Ireland now has the lowest COVID rate anywhere in the European Union, preparations for a vaccine, and these conversations about preparations for a vaccine, come as a very bright end, to what has been a very dark year for a lot of people. It's essential that when the vaccines are authorised by the European Medicines Agency, that as many people in Ireland get vaccinated as possible. That will need clear, consistent communications from trusted and expert sources. Dr Glynn has arranged this session to speak directly with you, your members and your organisations. Each of you has an important role to play in this crucial part of our country's response to COVID-19. Various parts of government have been putting in the ground work for months on a vaccination strategy; this includes the Department of Health, the HSE, the Health Products Regulatory Authority, the National Immunisation Advisory Committee, the National Immunisation Office, the Health Protection and Surveillance Centre, and others. The government also established a high-level taskforce on COVID-19 vaccination, not long ago, to support these efforts. The National COVID-19 Vaccination Strategy describes Ireland's high-level plan for safe, effective and efficient vaccination of the population, and it was agreed by cabinet. We plan to administer vaccines from long-term care facilities, hospitals, mass vaccination clinics, GP surgeries, and community pharmacies. This will be done by qualified and trained healthcare workers, who will administer the vaccine, including hospital doctors, community medical officers, nurses, GPs, and pharmacists. The vaccines will be rolled out in three phases; the initial rollout, a mass ramp-up, and then open access. At first, we will focus on the highest priority groups; those at the highest risk of contracting the disease, and those most vulnerable to the worst effects of the disease. Right now, we're all waiting for news from the European Medicines Agency, they're carrying out rigorous testing on the vaccines, to make sure that they meet quality and safety standards. The first vaccine they'll make a decision on, is the Pfizer vaccine. They said yesterday that they will meet on the 21st of December, and may decide whether to authorise it at that meeting. If the European Medicines Agency approves that vaccine, we can start rolling it out very shortly afterwards. It's really positive to be talking about vaccines now, and we want to be in a really good position, if and when they are approved. Unfortunately, along with this pandemic, we've seen an infodemic. There has been an overload of information, a lot of which has been unreliable. People have been exposed to a lot of misinformation, particularly online. We expect that these falsehoods will become even more common, if and when vaccines are authorised for use. It is more important than ever to counter this misinformation with facts, data, expert voices, and trusted voices. That includes all of you. You can all play a role in counteracting this infodemic, to ensure people have accurate and trustworthy information, so they can make an informed choice themselves. I want to thank you for taking the time to engage with Dr Glynn, Dr Nolan, and Dr O'Sullivan, and I really look forward to working with you all. Thanks.

Dr Ronan Glynn, Deputy Chief Medical Officer, Department of Health:

Hello everybody, and thanks for joining us for this information session about the COVID-19 vaccines, where we are at the moment, and where we hope to go over the coming weeks and months. I'm Dr Ronan Glynn, Deputy Chief Medical Officer at the Department of Health, and today I'm joined by Dr Lorraine Nolan, who's the Chief Executive of the Health Products Regulatory Authority, Deirdre Watters, who's the Head of Communications here at the Department of Health, and Dr Siobhan O'Sullivan, who is the Chief Bioethics Officer here at the Department of Health. So, our intention today is to give you some overall information in relation to the vaccines, the approval process, and what we think is likely to happen over the coming weeks. And obviously, to point you to where you can get more information, as that information becomes available. It's been a particularly difficult year for everyone, this pandemic has affected every individual, every family, every community in the country, in many different ways. And recent news on vaccines really is, I suppose, a positive development, and gives us very concrete reasons for confidence and for hope as we head into 2021. But we will have many challenges ahead, and one of the challenges I wanted to highlight to you today in particular, is this issue of misinformation and rumour, that we are going to have to tackle over the coming weeks and months. The World Health Organisation has been very clear that we're tackling two different types of challenge over the past year – one is the infection and the pandemic, but the other has been infodemic, which is really an excess of information, and excess of rumour, particularly online, which we've had to counter all of the time. And I think this will only ramp up over the coming weeks, as vaccines hopefully are rolled out, both in Ireland and globally. There are two types of information that we're concerned about; there's misinformation and disinformation. But I suppose, both can have a negative effect on people's willingness to take a vaccine, both can lead people to have unfounded concerns about these vaccines. So, it's very important that this misinformation, disinformation rumour is countered by all of the organisations, and by all of our healthcare professionals across the country, who'll be in position to do that, as we rollout these vaccines. One of the key reasons I think why we'll face challenges in this space over the coming weeks, is the fact that these vaccines have been developed so quickly. On the one hand, it's absolutely fantastic, we've never seen developments in science or in medicine on such a scale, on such an enormous level as we've seen over the past year. And really, from a medical perspective, it's almost unbelievable that a disease that we didn't know about, even one year ago, we now have vaccines about to be rolled out for. It really is a fantastic achievement, but that in itself will lead to uncertainty. And I know that a very understandable question that people have at the moment is, how has this happened so quickly, and as a result of it happening so quickly, have any corners been cut, and are these vaccines truly safe. And so, what I would say to that in the first instance is that none of the corners have been cut, there are many different reasons why these vaccines have been developed as quickly as they have. There's been enormous levels of investment, that investment has come on the back of decades of scientific and medical research that has allowed us to be in a position to capitalise on that investment. Many of the processes that are normally involved in vaccine development, and which run one after the other, have instead run in parallel. And as I'm sure you'll hear from Lorraine in a few moments, our

regulators have been actively involved in looking at the data for many months now, and they've worked with those developing the vaccines, so that the regulatory process can be as smooth as it needs to be. And again, that's not to say that any corners have been cut, all of the normal requirements that are required of any vaccine or any medicine that's going to be authorised and rolled out, all still apply in relation to these vaccines. There are very understandable uncertainties and questions, there's a lot we still don't know about these vaccines, and we have to be honest about that. We don't know, for example, about durability. So, what that means is, that at the moment we don't know whether people will need repeated vaccines over time. We also don't know at all really at the moment about the effect of these vaccines on transmission, so the trials that have been done tell us that if you get the vaccine, or if I get the vaccine, that's very likely to protect you or me from the severest effects of COVID-19, and we shouldn't get sick if we're exposed to the virus. However, what those trials haven't been able to tell us so far, is whether or not it stops us passing it onto another person. So, until we know more about transmissibility, all of the normal, the basic messages that we've been communicating to people for many months now, will still apply around handwashing, physical distance, wearing a mask where appropriate, avoiding crowds, all of those measures unfortunately will still have to apply for at least the next number of months. Both until we get more information about transmissibility, but also until a significant proportion of the population has been vaccinated. And I suppose again these are just the messages that we've been reiterating over the past year and unfortunately, we'll have to continue to reiterate those. Just one point I wanted to make is that you will hear a lot about misinformation, you will hear a lot about rumour. And frankly, there will be lies spread about some of these vaccines. There is a small but very vocal anti-vaccine group, both in Ireland and internationally, but it's very important that people realise that that's not the majority view. And indeed, our own research in Ireland suggests that somewhere between 70% and 80% of people in Ireland either will definitely take this vaccine when it's offered to them, or are likely to take it. Albeit that, as I said, they'll have justifiable questions that they'll want answered in the first instance. And our job is to make sure that that information is available to them. And a key way in which that information will be made available to them is through our healthcare professionals. Our doctors, our nurses, our pharmacists, they are the most trusted sources of information for people. So, where people are looking for extra information, in the first instance I would point them to the HSE.ie website, to immunisation.ie or to our own website here at the Department of Health, which is gov.ie/COVID. Or indeed to the HPRA's website. All of those sites have trusted information. But over and above that, people will still have very understandable questions and they will go their GPs, they'll go to their pharmacists, their nurses, and so it's our job to equip all of those healthcare professionals across the country with the information they need to answer those questions over the coming weeks. So, at this point, I might hand over to Dr Lorraine Nolan from the Health Products Regulatory Authority, to give you some extra information about the process to date and what's likely to happen over the coming weeks. Thanks, Lorraine.

Dr Lorraine Nolan, Chief Executive, HPRA

Thanks very much, Ronan, and if I might just begin by explaining a little bit about the Health Products Regulatory Authority and the role that we have. And we are the national agency that is responsible for the safety, the effectiveness, and indeed, the quality of medicines, including vaccines in Ireland. So, you've probably heard a lot about the European Medicines Agency and their role in relation to COVID-19 vaccines. Just to explain that some medicines, including vaccines, have to be authorised through what is known as a centralised procedure. And the reason for this is they are novel in nature, or indeed as we have with COVID-19 vaccines where these are being used to address a novel viral infection. They have to come through this centralised process. But it isn't the EMA that carries out the technical and the scientific evaluations; the EMA works by coordinating the expertise and the input from all of the national agencies. And that includes at member state level and within the EEA countries, all of the agencies like ourselves and the HPRA here in Ireland. So, if I can I'll just skip those two slides. So, Ronan has spoken a lot about the fastness of this process and we really know from all of the coverage that is coming up that there may be a concern about this having been a rushed process. So, the first thing for me to say to everybody is while this is an accelerated process, it absolutely is not a rushed process. These COVID-19 vaccines will have to meet the exact same standard, the exact same data requirements, as all vaccines. And in terms of the regulatory review, it will be every bit as stringent as that is applied to any vaccine in the normal circumstance, and indeed, any medicine in the normal circumstance. Europe has made the decision to stick to its established processes for assessing these vaccines. And that is to afford the highest standards of public health and protection and in particular, safety for these vaccines. But also because of the level of expertise and review that involves, I've explained how the EMA works through bringing in the expertise of the national agency. So, I just want to put this in context, in our agency nationally I have 50 people working on the assessment of these vaccines and COVID therapies in general. So that is our team of clinicians, our team of scientists, our pharmacists, our biostatisticians, our pharmacokineticists. So, when you multiply that by 27 member states, including the EEA countries, it gives you an idea of the pool and the scale of expertise that are looking at these vaccines. So that's from a safety and assessment viewpoint, that's the highest level of assurance that we can provide. So just to speak a little bit about the acceleration, and Ronan has outlined many of the factors that are involved, it's also fair to say that, and you've probably been hearing a lot of these, many of the vaccines that we're looking at are based upon the genetic material of the virus itself. So, the publication of the genomic sequence of this virus was a rapid enabler, and it really brought us through the very early stages of developing, enabling us to get into clinical trials in the investigation of these vaccines, much earlier than would normally be happening. So, this is a really nice visual slide here showing you the spike protein on the right, and on the left the genetic sequence of the protein itself. A little bit about the different kinds of vaccines that are under development, which may be of interest. We're using different types. So, I've spoken about these vaccines that are based on the genetic material of the virus, so on the bottom of this slide you can see the viral vector vaccines and the nucleic acid-based vaccines, and these are the messenger RNA. So, both the viral vector vaccines and the nucleic acid-based messenger RNA ones, as I said, work on the genetic material. So, in terms of the Messenger RNA one, the Pfizer-BioNTech vaccine and the Moderna vaccine fit into that category. The viral vector, as you've heard a lot about, the Astrazeneca, the Oxford the vaccine, indeed the Janssen vaccine as well, they are viral vectors. We also have

ones which are based upon the spike protein itself or a component of the spike protein, the GSK one and the Novavax vaccine fit into that. And then of course, more traditional vaccine technologies which are based around the inactivated virus itself. And all of these work by tricking the body into actually producing a response to the vaccine which gives the immunity to the individual. So, another thing that has really helped in the acceleration of the development cycle of these vaccines is the learnings from previous public health crises. And in particular the Ebola virus and the zika virus as well, too. And these may not be issues that have affected us in this part of the world, but really important learnings here for the scientific community in terms of how to construct clinical trials in terms of how to follow the waves of the pandemic so that you could have enough actual active infection to really run successful clinical trials. All of those learnings have really helped us in the acceleration. So now I'm coming to the regulatory process itself and a little bit around the product development cycle. So, what this slide shows you here on the left-hand side, and that's shown in blue, would be the standard development cycle for a vaccine or a medicine. So, you can really see here that begins with the characterisation of the composition of the vaccine itself, and I'm going to speak here in terms of vaccines, looking at its pharmaceutical quality. You then move on to the non-clinical tests, which are usually done in laboratories. And then you come in to the clinical trial programme, so phase 1 clinical trials, the early ones, which look at dose finding, phase 2 which look at the immunogenicity, and then phase 3, which are looking at the efficacy. And at all stages in those clinical trials, we are looking at safety as well. And then you can see in the blue, underneath the phase 3 trial, we come at that point to the scientific evaluation and authorisation. That is the point at which the companies normally make their applications to the regulators for a marketing authorisation, and once that approval is given, the companies then scale up the production and they really start to make supply available going on to the marketplace. And then there can be some studies after authorisation. On the right then we turn to what has happened in the case of these COVID-19 vaccines. You can see the development cycle has been much more compressed and you have overlapping stages. So particularly looking at the clinical trial area, the phase 1, the phase 2, and the phase 3 clinical trials, you can see in this situation where these have been overlapping and where we come in, and you can see underneath that, is the scientific evaluation and the authorisation. So, what has been happening with these COVID-19 vaccines is the engagement with the regulatory process has been happening continuously throughout the development cycle. And the reason we do this is that it allows the manufacturers, or the developers rather, to submit to us their data packages in real time, and we are reviewing those. And that tells us a couple of things; first of all, it tells us the point at which the company has enough data to make the submission, so that's incredibly important in terms of the acceleration. But also, it familiarises the regulators with the data package, and a lot of the review then is frontloaded and it's done in line with the development cycle. But a really key point, and this is the point that no corners have been cut, no lowering of the bar in standards, is that the data packages and the data level is still exactly the same under this compressed accelerated process. And you can see then the large-scale production, that starts to happen in advance of the regulatory approval. And that's why when these vaccines are authorised, we do have stocks to go, they are limited in availability but there is some supply to push it onto the marketplace. And the manufacturers do this at risk and then there are studies after authorisation. So, it doesn't stop then in terms of the regulatory approval once the product is authorised and as I've said, the safety of the vaccines is monitored throughout the clinical trial programme; the

phase one trials, phase two, phase three. They all give us information on the safety of a vaccine. So, most reactions to a vaccine will occur within six weeks of vaccination. So, all of that data will be available to regulators when they're reviewing and if we spot anything there that is of concern these products will not receive an authorisation. So, obviously very reassuring that the UK have given an authorisation to the Pfizer vaccine at this point and we've seen the US have done this similarly. But the one thing I have to say is that when you move from clinical trials which are conducted on tens of thousands of people as in a phase three, into a situation where a vaccine is used in millions of people and indeed billions of people during a pandemic, you can never ever absolutely eliminate the fact that when you move into that scale of usage in billions of people that something may show up, something very rare, you'd be talking about a probability of less than one in a hundred thousand which might occur. But what we're doing is weighing that up against the very, very real risks presented by the COVID virus itself. I mean one in 40 people that have been affected with this virus have died. And we know in Ireland, 8% of people that have contracted COVID have ended up being hospitalised. So, in 100,000 people that would be 8,000 people hospitalised. So, when you weigh up those risks, any potential theoretical and very rare risk of a vaccine is definitely significantly outweighed by the risks of the disease itself. And, one of the things we do when the vaccine is put into the marketplace is, we extensively monitor and we monitor the safety of the virus, or the vaccine rather, in the real-world setting. And that's another of the roles that is carried out by my own agency, the HRA. So, just to put this in context, what happens we routinely monitor all medicines and I mean that risk I'm talking about when you go into the real world, that exists for every medicine, every vaccine. We routinely monitor and that's done through getting reports back in from the public and from healthcare professionals and this is something we would really like support with in terms of encouraging people to report any information on effects to us, to the HRA and the information is on our website how you can do that. We will also be working with healthcare professionals to encourage reporting on this. So, we analyse that data, we provide that data into the European Medicines Agency and the main safety committee looks at all of those reports. You have to remember this will be done on a global scale by other regulators and all of that data is pooled and the reason we do that pooling and that analysis is to really pick up as early as possible anything that is maybe unexpected in relation to this widespread use of the vaccine as well. So, just in a little bit in terms of where we are. At the moment and the EMA has publicly announced, the Pfizer BioNTech vaccine, we are now expecting at this point that the main Human Medicines Committee will convene an extraordinary meeting on 21st December. All going well at that point, the EMA may be able to conclude the scientific review and evaluation of the Pfizer vaccine. If not, they have held a date of 29th December to conclude at that process. But if the opinion is positive on 21st December, we'll very shortly move to having a marketing authorisation granted within a couple of days by the European Commission. The Moderna vaccine looks likely to be the next vaccine that will be authorised in Europe and at this moment we are expecting the Moderna vaccine, for the committee to meet at the EMA on 12th January. Depending on the outcome for that we may shortly have an authorisation of the Moderna vaccine after that. And then the Oxford–AstraZeneca vaccine and Janssen, they are undergoing the rolling review process currently at the EMA and we will have more information on those two vaccine candidates early in the new year. So, that's it from me and thank you. I'm going to pass you over now to Deirdre Watters from the Department of Health.

Deirdre Watters, Head of Communications, Department of Health

Good afternoon everybody. My name is Deirdre Watters and I'm the Head of Communications here in the Department of Health. I'm just going to take you through the communications programme that we've established for the vaccine and I guess the first thing that we need to do is just to understand the context that the vaccine is coming in. And we know that over the past year, throughout the pandemic, that we've been able to build significant trust in the public health advice that has enabled people to protect themselves from COVID-19. And you'll be familiar with our COVID yellow, as the whole country is familiar with, which through our strategy of openness and transparency had engender a lot of trust and people are happy to, people know now that this is coming from a trusted and a safe place and they're happy to work with us and work with us on the public health advice. We are also in our communications plan, incorporating significant insights that we've had from the HPV anti-vax campaign a few years ago. So, Ireland is one of the few countries that is successfully addressed a significant anti-vax campaign against the HPV vaccination. Our colleagues in the HSE have got significant insight in how that worked. And so, we know what we need to do are really three things. Listen to the public, listen to the concerns and the genuine questions that they have, acknowledge them and address their fears. When we come to deliver our clinical advice, we do so with empathy and understanding where the public are coming from. And then thirdly, make that vaccine logistically easy to access. We do know that when we take all of these insights and we bring them into our comms for the vaccine, it is important that we understand that as Mike Ryan from the WHO has said, 'The arrival of vaccines for COVID do not mean that we are in a zero COVID-19 world. We will still need to add the vaccines to our public health advice. We will still need to wash out hands, social distance, wear face covering and until the vaccine rolls out across the country, we are still going to have to work with the public health advice'. And so, from that perspective, what we're doing in our COVID communications is we're incorporating the vaccine into our public health advice and our public health advice is just going to expand. The COVID vaccine is another tool that we are adding into our toolkit. And so, from our communications objectives, we've split it into two phases. So, phase one which we're in now is about preparing for the vaccine. And it's about understanding public sentiment on an ongoing basis, understanding what people are thinking about feeling about the vaccine and building those insights into how we're talking to them. And we know already some of the insights we've gotten is, as both Ronan and Lorraine were saying, the public are concerned. They've got genuine questions around the vaccine and they want to know that the vaccine is safe. People know that historically it's taken five to ten years to develop a vaccine, tell me why now in this instance we've done it within five to ten months. And so, as Lorraine has just taken you through, we will be reassuring the public again and again as to the process around the development of the vaccine, sharing data when it is available from the clinical trials. Sharing that data, making it as available, and making it accessible for people to get to. And addressing, answering what we know and also, as Ronan was saying what we don't know. Just yesterday, we had the communication of the Government plan. Again, this is what the public want to know. So, tell me about the drugs or the vaccines that Government is acquiring, tell me who's going to get them in what order and tell me how I am going to get it when it comes my turn to get the vaccine. And again, as Ronan was saying, stakeholder communication is really, really important. We do know that when it comes to the vaccine, communication at a very local level is going to be really, really important because people trust people. People will be asking their GP, their nurse, their pharmacist, they'll be asking

them for information around the vaccine and so that's why events like today and there will be more communication out to all of our stakeholders to share with you, as soon as we have information, we will share that with you so then you can share it out with your patients, with your public. We're also at the moment very busy developing our campaign material around the vaccine. So, both on HSE.ie and on Gov.ie you'll find vaccine pages. We're creating video explainers, FAQs, etcetera, which are there now. And then we're also working on material that we need to have for phase two when we rollout the vaccine. And so, phase two which will begin early January which is around implementing the vaccine programme. So, when we come to do that there's a number of different elements within this part of the campaign. So, national and local PR and social media leading out with our public health, our immunisation, our medical experts, explaining what the vaccine is, again addressing any fears, any questions that people may have, and encouraging vaccination, encouraging vaccine uptake. We will also be tailoring our communication to the priority cohorts. So, you will be aware of the sequence that's been laid out for vaccination and we will be doing tailored communication to each cohort as their turn comes. Again, giving them all of the information that they need to make the decision, their own decision around vaccination. We'll be talking to the logistics of accessing a vaccine. So, when it's your turn to come you'll know where to go, what to do. We're looking at identifying people of trust to act as ambassadors for vaccination and we know that those people of trust are primarily your local healthcare workers, they are your GP, they are your pharmacist, they are your public health nurse. That's who people are going to trust and so working with our healthcare professionals is really, really important to us so we will be doing a lot of local communication. Again making as much information as we have as available and as accessible to everybody. And then once we finally get there, once we start the vaccination programme, we'll be reporting on a regular basis in the same way we do all of our COVID news. As I said at the outset, what's really important is that the whole way through this pandemic, we understand what people are thinking and feeling. We've been doing it from February, we have our weekly Amarach tracker, where the data goes up on our website every Monday. We're doing on-going qualitative, so focus groups, depth interviews with different cohorts across the nation and we also work with the Behavioural Research Advisory group who've been helping us - if you think of you know where we've come to today, where everybody as a nation are now sneezing into our elbows, something this time last year, we never ever did. So, our behavioural research team are helping us to again, to tailor our communications to make sure that we can give people all of the information they need, we can empower people to make the decisions that they want to make to protect themselves and their families. So, understanding what people are thinking and feeling the whole way through the pandemic is really, really important to make sure that we can continue to keep people working with the public health advice. And we are working from a visual perspective. So, again everybody in the nation will be very familiar with our COVID yellow, which is the public health advice. And our yellow posters that have been the whole way across the nation. This has now been evolved into a new colour for the vaccine. So, our vaccine is, it's blue but you'll see, you'll have seen from the charts earlier that the blue and the yellow are working together because we do know that the vaccine is coming into our yellow, the vaccine is going to be part of our public health advice. And there are risks, again, as both Ronan and Lorraine have acknowledged, there are issues that we need to make sure that we are aware of and that we're incorporating within our whole communications campaign. First and foremost, if people think the vaccine is a silver bullet and that it's going

to eradicate COVID overnight, we know that's not the case. And so what we're doing is building a bridge from our existing communications into bringing the vaccine within our public health advice to make sure that people understand it's an additional tool, it is not a silver bullet. We know there are public concerns around vaccine safety and we're working very closely with Lorraine and her team in the HPR, to help people understand the process around how the vaccine has been developed, to help people understand that safety has not been compromised in the development of the vaccines that are going to come on the market in the New Year. Vaccine hesitancy, that's why we're here today and asking you just to help us address any genuine concerns that people may have and we will pre-emptively debunk misinformation and tell people where to go to, to get the right information that they need to get. Another risk that we're working towards is making sure that the logistics around access to the vaccine and our communications for the vaccine that they'll work together so we can make sure that people know what to expect and when. And then last but by no means least we do know there is going to be significant interest in vaccine uptake from the media, from the public, from everybody across the country. So, we will be doing regular reporting by geography, by priority group, et cetera and we'll be making that available online. So, thank you for that. I'm now going to hand over to Siobhan. Thank you.

Dr Siobhan O'Sullivan, Chief Bioethics Officer, Department of Health:

Good afternoon, everybody. I'd like to talk a little bit about the allocation framework that we have developed for vaccines. We know now that the availability of a safe and effective vaccine is a major step forward for all of us, in terms of both our health and our society and economy returning to some form of normalcy. But it's really important that we – the objective of vaccination is really to ensure that there is equitable access to safe and effective vaccines, that we limit very serious illness and death in our population, and we can try and get back to some sort of social and economic activity. So, vaccination is really one step on the road to that, a very important one. So, we need – we recognise that initially there will be limited availability of vaccines as Lorraine has said. So, there needs to be a process by which we can determine who should in fact be able to access these vaccines initially. Clearly the objective is that everybody for whom the vaccine is indicated will be given an opportunity to receive the vaccine but this is during this very initial period when supplies are limited. So, it's important also to, as Deirdre has said that the vaccine is one part of our general strategy in terms of COVID, a very important one but one part. And therefore we, in thinking about how we would allocate vaccines during this period of kind of scarce resources have had to think about how that fits into the general kind of strategy. So, can people find other ways to protect themselves? Can they easily socially distance? Can they isolate? Can they wear PPE, etcetera? So, we need to see it as part of that broader strategy. So, priority setting has consequences, very significant consequences for people's health, for their quality of life. So, while it's clear that we need to use all of the best information available to us, there also has to be a recognition that there's values at stake here and that the people that are accelerated in terms of receiving the vaccine that we need to have very clear recognition of the values that are at play here and why we are vaccinating certain groups in order or priority. So, in terms of how this has been done, the Department of Health has been working with experts in the National Immunisation Advisory Committee to ensure that based on the very best and most recent epidemiological scientific evidence that we know who are the groups that are most at risk from very poor outcomes in terms of if they get COVID-19 but we've also superimposed that in terms of looking at what are the

ethical values that we need to bring to bear in terms of these decisions. And so, we have rooted our evaluation in our ethical framework for decision-making but also in the WHO, the World Health Organisation framework values framework, to ensure that we bring to bear those ethical principles that are really important in making these very important decisions. So, we really believe that using these ethical principles to guide this kind of decision-making so using both the best scientific available information as well as these ethical principles can really persuade people that actually we're doing this in a way that is fair and equitable. So, I just wanted to address with you today some of the and bring you through some of those principles that we're using. So, in coming to the allocation list, you will have seen published earlier we have taken a number of different principles. The first one is moral equality and at its very simplest, what we're recognising there is that everybody is equal, everybody is deserving of respect and everybody who can get the vaccine, for whom it's indicated, should get the vaccine and we're not discriminating on the basis of social worth or other kind of factors like that That everybody is entitled to equal respect and dignity.

The next principle we're using is minimising harm. So, that's a very classic public health principle where we try to minimise the harm that people actually experience. Now we're considering harm in a very broad way here, both in terms of health, but also in terms of social and economic consequences, because we know the impact that this pandemic has had on people, and that's people in all of those either through becoming very ill, or perhaps losing their jobs, or educational or employment opportunities. So, but it is important to say that in the first instance we are looking at very serious and irreversible harm, and of course death and very serious disease is a very good example of that.

The next principle we've used is fairness, and I suppose really at its most basic we are saying that everybody who should, there should be no disproportionate burden or indeed benefit to any individual or group, and that everybody who's entitled to have the vaccine should be able to avail of it. And in terms of fairness, we do know that there are certain people who have been disproportionately affected by this pandemic and therefore there is an obligation on us to ensure that we actually pay special attention to the needs of those individuals.

Finally, the principle of reciprocity, and this basically at its heart is saying that we have a moral obligation to help those who have helped us. So, there are people who have taken on additional risks in trying to protect the rest of us in society, and therefore there is an obligation that we now protect them.

So, what you also see on the slide is a series of procedural values and that is simply setting out that not alone the decision that we make, i.e., who we've prioritised, but the way in which we reached that decision is very important. And so, they set out things like transparency, inclusiveness, responsiveness. We really need to be going back and looking at the evidence on an on-going basis to ensure that we're making the best decisions possible.

You're probably all familiar now with the provisional vaccine allocation groups, and what I just wanted to say was something about those that we have initially, during this very initial period, those who have been prioritised and the rationale and the reasoning for that.

So, in the first instance you'll be aware that older persons have been prioritised and especially those in long-term residential care, and the reason for that is that we, all the evidence indicates that the worst outcomes are really amongst those who are in the over-65 category. So, irrespective of anything else age is a very good indicator for how severely affected a person will be if they actually contract the virus. So, we have paid particular attention to that very vulnerable population. Again, in the first instance it's really directed towards those in long-term residential care, and that's in recognition of the fact that they are in an area and in a space, living together in communal spaces where it might be very difficult for them to actually socially distance or take other measures to protect themselves.

The next category that you'll be aware have been prioritised are Healthcare Workers, and that's basically on the basis that we know that Healthcare Workers are at an increased risk of exposure and that they are also, there's a multiplier effect, if you like, in terms of vaccinating Healthcare Workers, because if it turns out that these vaccines do interfere with transmission, this means that we will by protecting our Healthcare Workers also indirectly protect those who they care for, who we know are the most vulnerable amongst us. There is also that issue of ensuring that we can maintain our healthcare, health and social care services. So, these are the people we need to be able to keep those services going, so that the rest of us can actually receive the care that we require. And again, this is really in recognition also of the fact that they have taken on this additional burden to care for us.

Finally, then we're looking at the group who have underlying conditions, which we know from the evidence place them at particularly high risk of actually having a very poor outcome if they contract the virus. So, we know for example that there's good evidence around those with chronic lung disease or heart disease, hypotension, diabetes, obesity, and a number of other conditions which place you at increased risk of having a very poor outcome if you in fact contract the virus. So, in the first instance we are going to look at people who are in the older age group and who have an underlying condition, because as I mentioned age is really the very key factor here in terms of poor outcomes. So, looking at those groups first, and then going, after we've managed to vaccinate those groups, then taking care of those who have an underlying condition, as I say that puts them at additional risk, but maybe in a younger age category.

So that sets out the kind of initial reasoning or rationale and very much speaks to those four ethical principles, ensuring that we minimise harm, that we take decisions that are fair, that we have reciprocity and that we recognise the moral equality of each and every one of us in our population. So, I think the important thing to say is that the vaccine allocation strategy is very much a living document. This will be constantly updated as we receive new information. It's really important that we have an agile response so that we are able to ensure that we can vaccinate the most appropriate people in the priority groups depending upon the vaccine characteristics and the availability that we will have of different vaccines. As Lorraine has explained, there will be different vaccines coming on-stream at different points, so it may very well be that we end up vaccinating people in parallel for example, or in slightly different ways, and if we receive information, new information, we will ensure that we keep the document up to date as appropriate.

The last thing I'd like to say is that much emphasis has been placed, I suppose, on the prioritisation process, and that's entirely understandable, but I think we really need to think beyond that and also ensure that in the distribution of this vaccine that we're really, it's really important that we ensure that equity is maintained there. So, we know that there are going to be many groups who can be hard to reach, for example the marginalised in our populations, and it's really important that we ensure that in terms of rolling out this vaccine campaign that it's not only about prioritising those individuals for vaccines, but doing it in a way where we reach out to them in a way that they can trust and that is in a practical way, easy for them to engage with. So, equity being very much a focus for us in terms of how we roll out this vaccination campaign and in deciding who becomes vaccinated first. But to finally end and say it is entirely the objective and the aim that everybody for whom the vaccination is indicated will receive it, and that this prioritisation is very much in keeping with scarce resources at the very beginning of this process. Thank you very much.

Dr Ronan Glynn, Deputy Chief Medical Officer, Department of Health

Thanks very much, Siobhan, and thanks Lorraine and Deirdre. So, just to summarise I suppose. I hope you've found the information that you've received during the session useful, and we can certainly plan to do more of these over the coming weeks and months if you have found them useful, but of course we do have an ask of you, but just before I get to that I suppose, first of all I want to say thanks, because it has been an incredibly difficult year and we have no doubt that without the massive buy-in and support of all of the organisations who are participating in our response to COVID, we simply wouldn't have had a chance of controlling to the extent that we have had. So, first of all I just want to say thanks for all of the work that you have done through your organisations over the past year. But there is an ask, because we're not through this yet. We are going to be living with COVID for the foreseeable number of months at least and I suppose the key to moving past this pandemic is ensuring that we have a successful implementation of a vaccination programme. What we want, or what we're hoping that we can achieve in this country is an open, transparent dialogue, that everyone understands the reason why particular groups have been prioritised and that people buy in to that and then when it comes to their turn, that they're enthusiastic for and willing to get vaccinated themselves. We do need to manage expectations and we need everyone to help us with that. Not everyone is going to get vaccinated on the 1st of January. It's going to take a number of months at least to roll this out, and as I said earlier, in meantime we need to keep going with all of the other public health measures that are so important. We need to be honest, as I said, about uncertainties – we don't have all the answers at the moment, but I suppose our commitment to you is that as this information becomes available, we will, we will make that available across the country, and again I'll just take this opportunity to direct you to the immunisation.ie, to gov.ie/covid, to the HPRAs website. All of those are really good, trusted sources of information that will have the most up to date information at a point in time. As I said, I'm sure many of you listening to day have, still have after this session will have many questions, and those questions are very legitimate, they need to be answered and as we get the information, we will endeavour to answer them to the best of our ability over the coming weeks. I suppose finally we believe that personal anecdotes will be very important, that a focus on local messaging, Healthcare Professionals living and working locally are going to have a huge role, but your organisations and the roles that you play in communities all across the country will also have a fundamental role to play in this, just as your

organisations, as I said, have had a fundamental role to play over the past year. So finally, I just want to say thanks again for joining today. I hope it's been of value, and in the first instance, as I say, go to the websites that I've mentioned for more information and we will do more of these sessions over the coming while to ensure that everyone who needs the information has access to that information. Thanks very much.

ENDS