



Directorate for
Civil Protection and
Emergency Planning



REPORT

New influenza A virus (H1N1)

A summary of a study on the
national response in Norway

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NEW INFLUENZA A VIRUS (H1N1)

A summary of a study on the national response in Norway

CONTENTS

FRAMEWORK AND BACKGROUND	5
HANDLING AT THE CENTRAL LEVEL	7
Control, planning and coordination	7
Choice of governing strategy	7
Surveillance and assessment	8
Prevention and containment	8
Use of antiviral drugs	8
Vaccination.....	8
Treatment	9
Other functions of importance to society	9
Communication.....	10
HANDLING AT THE REGIONAL AND LOCAL LEVEL	11
Control, planning and coordination	11
Vaccination.....	11
Treatment	12
Conclusion – lessons learned	13
Which challenges would Norway have faced in a worst-case scenario?	15
DSB’s recommendations.....	16

FRAMEWORK AND BACKGROUND

On Friday, 24 April 2009, the World Health Organization (WHO) issued an alert concerning an outbreak of influenza caused by a new virus in Mexico and the USA. This new virus saw the start of a new global epidemic which spread across the world during the next year, giving large parts of the population an influenza illness. In Norway the first cases were reported as early as the beginning of May, while the main wave of the illness struck the country in the second half of October and first half of November 2009. Estimates indicate that as many as 900 000 people in Norway may have caught the new influenza A virus (H1N1). For most people, the influenza was like a mild illness, but some were hit hard. By the end of 2009, we had recorded 29 deaths due to the new influenza A virus (H1N1) in Norway.

The response to the pandemic caused by the new influenza virus involved the entire Norwegian health sector and the majority of Norwegian society. The response consisted of essential activities such as planning and organization, reporting, providing the public with information as well as treatment and vaccination of special risk groups and the population in general.

The Directorate for Civil Protection and Emergency Planning (DSB) has been assigned the task of coordinating a study of the national response to the pandemic for the purpose of drawing on lessons learned nationwide, thus improving our future response to pandemics. Key issues are related to the choice of national strategies and measures, and how these should be implemented. This includes aspects such as planning and preparation, organization, analysis of the situation as well as communication between the authorities, the health sector and the population, and how the coordination worked on different levels. This review has been carried out in close consultation with the involved parties.

The methodological basis for the review is mainly comprised of:

- Continuous dialogue with key players within the framework of a collaboration group consisting of representatives from the Norwegian Directorate of Health, the Norwegian Institute of Public Health and the Norwegian Medicines Agency. At every other meeting the group was enlarged with representatives for regional and local entities.
- Meetings with key entities on the national, regional and local level, including health trusts (HF), county governors and municipalities.

- Reviews of documentation from key entities and other sources
- Implementation of three surveys with questionnaires issued to the regional health authorities (RHF), County Governors and municipalities.

The various laws and regulations, plans and routines, etc. set the framework and premises for the handling of the pandemic at its outbreak. *The Act on health and social preparedness* instructs the municipalities, County Governor Offices, regional health authorities (RHF) and the national government to draw up preparedness plans for the health and social services for which they are responsible. *The Act relating to the municipal health services* sets out that the municipalities shall provide the necessary health services for all persons resident or temporarily domiciled in the municipality. Pursuant to the *Act on the specialist health services, etc.* the regional health authorities shall ensure that persons resident or temporarily domiciled in the health region will have access to appropriate specialist health services, and also that preparedness plans are drawn up.

The Act relating to control of communicable diseases assigns the Norwegian Directorate of Health an important role in the control of communicable diseases. When so required, the directorate may instruct the municipalities, county governor's offices or government institutions to organise or carry out certain specific services or measures. The Act decrees that the Norwegian Institute of Public Health (NIPH) must monitor the epidemiological status, secure the requisite supplies of vaccines and set up vaccination preparedness. In addition, the institute is to provide assistance, advice, guidance and information to institutions on a municipal, county municipal and national level, as well as to medical personnel and the general public. The Ministry of Health and Care Services (MHCS) will determine a nationwide vaccination programme for communicable diseases, and the primary health care in the municipalities will supply this service to the population. The regional health authorities must make sure that the population in their region receives the necessary examination, treatment and appropriate isolation in hospital as required. The principles for a central crisis management are laid down in the Storting report no. 37 (2004-2005) *The tsunami disaster in South Asia and central crisis management*.

This Storting report states that the Ministry of Health and Care Services will assume the role of lead ministry in crises relating to epidemics/pandemics. In a crisis situation, the lead ministry will i.a. prepare comprehensive situation reports, identify and assess the need for measures at a strategic level, ensure that the necessary measures are initiated within its own area of responsibility, ensure necessary coordination with other ministries and see to it that coordinated information is given to the media and the general public.

The comprehensive national health and social preparedness plan describes the roles allocated to the entities that will be involved in the health and social care administration and the health and social services during crisis and disaster situations and in the emergency preparedness planning. The plan states that the Norwegian Directorate of Health will be authorized by the Ministry to manage the general coordination of the response efforts of the health and social services and, if necessary, implement measures when a crisis situation is impending or has taken place.

The Norwegian National Influenza Pandemic Preparedness Plan (the Pandemic plan) underlines that the responsibility for handling a pandemic follows the principles for crisis management that apply to the health sector and society in general. The plan is based on WHO's categorization into phases related to contagion as this was in 2006, and outlines the goals and measures for each of the six phases. The plan recommends vaccination as the best measure to prevent people from falling ill.

Following a bidding round, an agreement was entered into in June 2008 on vaccine deliveries. The agreement entitled and obliged Norway to purchase pandemic vaccinations, and comprised a total of 9.4 million doses at a price of NOK 730 million. According to the contract, the vaccine deliveries should start up as soon as the manufacturer had produced a vaccine, and continue with weekly supplies until the full quantity had been delivered. Norway would receive a fixed proportion of the manufacturer's production. The agreement was called when the WHO declared phase 6 (pandemic) and gave no room for renegotiation based on the gravity of the illness and the situation in general.

In spring 2009, the Norwegian Institute of Public Health (NIPH) published planning guides for mass vaccinations in the municipalities and health trusts. The guidelines specify roles and responsibilities and tasks, and also draw up strategies that might be relevant, ranging from no vaccination at all to a full-scale vaccination of the entire population.

Key issues in the survey of the nationwide handling of the pandemic are mainly based on the principles and objectives set down in the Pandemic plan:

- control, planning and coordination
- monitoring and assessment
- prevention and containment
- response
- communication

The findings in this review are evaluated based on how far they can help society handle a new pandemic in the best possible way.

HANDLING AT THE CENTRAL LEVEL

CONTROL, PLANNING AND COORDINATION

In the Government's crises council on Monday 27 April, the MHCS was appointed lead ministry. The way the situation progressed meant that the need for coordination at Ministry level was fairly low. At a meeting on 27 April, the MHCS verbally delegated the responsibility for the overall coordination of the response by the health sector during the pandemic to the Norwegian Directorate of Health. The Directorate regularly reported on the situation to the Ministry, and there was also regular informal contact during the period.

DSB is of the opinion that in general the overall control and coordination of the pandemic was handled well. Nevertheless, there are certain elements that might be queried, especially as these could represent potential weaknesses in the event of another and more demanding response situation. The general impression is that the MHCS appeared to be somewhat vague in their capacity as lead ministry, in part because the Ministry was careful about expressing what they expected from other ministries, and partly because the responsibility for the overall coordination of the health sector's efforts had been delegated to the Directorate of Health.

It was unfortunate that the MHCS's delegation of the responsibility for handling the situation to the Norwegian Directorate of Health was not formalised, and that different opinions exist as to whether the decision applied only to the health sector or whether it also comprised some of the MHCS's role as lead ministry across the various sectors. Despite this, the DSB is of the opinion that the crisis management executed by the Norwegian Directorate of Health was performed with great commitment and professionalism. All the same, there is a need for a higher formalisation of the cooperation relationships and processes to prevent roles from overlapping and ensure high-quality decision-making.

Throughout the whole response effort to the pandemic, the Norwegian Directorate of Health and the Norwegian Institute of Public Health maintained close and extensive cooperation on most important issues. Pursuant to the Act relating to control of communicable diseases, the NIPH is responsible for securing the necessary supply of vaccines and the vaccination preparedness. The Norwegian Institute of Public Health

appeared as the Directorate's most important professional advisor through its surveillance of the situation nationally and internationally. We found that the Norwegian Institute of Public Health handled the situation in a professional and highly competent manner. With regard to communications, the cooperation between the Norwegian Institute of Public Health and the Directorate of Health was so close as to make the two agencies seem practically as one unit.

The cooperation between the Norwegian Directorate of Health and the Norwegian Institute of Public Health in handling the pandemic was close and efficient in most connections. There still seems to be an important issue that has not been clarified when it comes to how far the NIPH's role extends as an administrative agency for vaccinations, and on the other hand, how far the Norwegian Directorate of Health's general authorities go with regard to handling the overall coordination and implementing actions. This issue is of relevance to for example the set-up for distributing vaccines and prioritizing which groups should be offered the vaccines. Had the situation turned out to be more severe, the fact that the two agencies have their own separate communication channels to the first line health services in Norway could have constituted a challenge.

Together with the NIPH, the Norwegian Medicines Agency (NMA) regularly attended the meetings in the Norwegian Directorate of Health's crisis committee from August onwards. The NMA played an important part with regard to the approval of the Pandemrix vaccine.

CHOICE OF GOVERNING STRATEGY

It appears from the Pandemic plan of 2006 that vaccination of the population is the main strategy when handling a pandemic. The situation at the time the Pandemic plan was prepared was that the biggest risk was deemed to be a new pandemic caused by an avian influenza virus, because this virus presumably would inflict serious illness in a high number of people. Consequently, an agreement was entered into to procure vaccines. The Norwegian approach is mostly the same as that adopted by other European countries. As far as DSB can see, the authorities handled the pandemic predominantly in line with the strategy drawn up three years before.

SURVEILLANCE AND ASSESSMENT

The Norwegian Institute of Public Health set up a system for surveillance of the influenza A virus on a national level. The duty to report for health personnel, receipt and analysis of laboratory samples from all over the country and influenza surveillance of 201 doctor's offices (the «watch tower doctors») were important elements of this system. The Norwegian Institute of Public Health provided updates of the situation in its status reports. The Institute reported early on that it thought the pandemic would turn out to be mild with low lethality.

To better dimension the efforts in the health sector and society in general, it was necessary to have a plan scenario as a starting point. It gradually became clear that the probability of the worst-case scenario from the Pandemic plan was so insignificant as to make it necessary to draw up a new plan scenario. Therefore, the Norwegian Institute of Public Health presented a new plan scenario at the end of July 2009, based on what was assumed at the time to be a reasonable worst case approach. The plan scenario was modified in the beginning of September.

The NIPH's assessments of the most likely course of events turned out to largely correspond with the actual turn of events in Norway. In hindsight, it would seem reasonable to ask whether the proportion of sick people who would be needing hospital treatment and intensive care was estimated somewhat too high in the planning scenario. Experience from Australia and New Zealand where the main wave of the pandemic struck at an earlier stage than in Norway, indicated that the illness was mild in the majority of cases, but that a few people were taken seriously ill.

PREVENTION AND CONTAINMENT

The Pandemic plan describes various measures against contagion aimed at delaying the spread of the disease, flattening the epidemic curve and reducing the numbers of infected and dying people. Several measures were implemented, such as giving advice on hygiene and staying at home. More drastic measures, such as closing down schools and pre-schools were not carried into effect.

The advice on hygiene is presumed to have been effective, although the actual effect is hard to measure. The advice was seen as relevant and taken onboard by the public to a large degree. The recommendation that people with influenza symptoms should stay at home for seven days is more debatable. At the early stage, when only a small proportion of people who had caught flu actually were infected with Influenza A, the recommendation led to higher absence rates than necessary.

The recommendation was more relevant at the later stage, when practically all the infected patients had contracted Influenza A.

USE OF ANTIVIRAL DRUGS

At the outbreak of the pandemic, Norway had stockpiles of the active medicines Tamiflu and Relenza. As of the beginning of May, regular reporting was initiated regarding the quantities of Tamiflu ordered by the pharmacies. From November 2009, the public could buy the medicines only on prescription from their GPs. From 5 November, the pharmacists were allowed to prescribe Tamiflu. This measure was put in place mainly to relieve the GPs.

VACCINATION

Because the vaccine deliveries to Norway were drawn out over a period of several months, it was necessary to distribute the vaccines to priority groups, in accordance with the Pandemic plan. In the first round it was determined that exposed health personnel and risk groups should be vaccinated first. That decision was made in the middle of September 2009, with the vaccination rounds starting up a month later. In the second half of October the recommendation was issued to vaccinate the whole population.

DSB finds reason to question the process in relation to the recommendation on mass vaccinations in October 2009. Only the members of the Pandemic committee were given the opportunity to voice their opinions, and in practice, the time limit for comments was only one working day. The report which the recommendation was based on did not contain a clear analysis of the cost-benefit ratio, when also taking into account the risk of side effects and the consequences of a recommendation to vaccinate the whole population. In addition there are different opinions as to who are formally responsible for the decision to recommend that the whole population take the vaccine, which in turn serves to illustrate the lack of clear-cut boundaries between the Norwegian Directorate of Health and the NIPH's area of authority during the pandemic. However, there is no doubt that the central entities, including the Ministry, agreed with the advice that was given.

DSB is not in a position to decide whether the advice to start mass vaccinations was right or wrong, but feels that the decision is fully understandable based on the actual situation in the autumn of 2009.

Following regulations which became effective on 5 October, the municipalities were instructed to offer vaccinations at a price of NOK 50 each. This was met with protests from the municipalities and the GPs who argued that this price would not cover their costs. The regulation was amended on 15 October, and the municipalities were allowed to set their own prices for the vaccinations.

It is the opinion of DSB that the pricing of the vaccination came too late, and that it did not have sufficient support locally. It was also unfortunate that the price varied between municipalities, and in many cases also between GPs and the municipal health services. In practice, people in the risk groups often ended up paying more for their vaccination than others, as these were to a larger extent vaccinated by their GPs. The vaccination coverage would most likely have been more extensive had the vaccine been given away for free, as they did in Sweden.

Once the first deliveries of the vaccine arrived in the country in the middle of October, the Norwegian Institute of Public Health started distributing them to municipalities and health trusts. The distribution of the vaccines continued until the end of February 2010, at which stage more than 3 million doses had been supplied. The transport was handled by a hired company. The distribution of the vaccines has been criticised by the receivers based on inadequate information and unpredictable deliveries.

DSB considers there to be several reasons for the problems experienced in distribution, among these are causes outside the health authorities' control. All the same, it is clear that the chosen set-up with the distributor that was selected did not work out well enough. Plans should be made for a more robust scheme for distributing vaccines, to be better prepared in this area when the next pandemic arises.

The NMA approved the vaccine after the EU Commission had done the same on recommendation from the European Medicines Agency. As of 1 April 2010 there were 1 049 reports of suspected side effects of Pandemrix. This figure is no higher than expected. Reports concerning an affect on the sense of taste were unexpected and previously unknown. Whether there is a connection between reported cases of narcolepsy and the vaccination remains uncertain at the present point of time.

TREATMENT

Based on the plan scenario presented at the end of July 2009 (reasonable worst-case scenario), the regional health authorities were asked to plan for an increase of the treatment capacity, with regard to equipment as well as personnel. In

particular the capacity for intensive treatment of acute respiratory distress syndrome was considered critical. The Norwegian Directorate of Health estimated a need for more than 1 000 intensive care places in the period of the highest demand, while there would be just less than 300 of these places in Norway in a normal situation. Respirators were purchased to increase treatment capacity, but the health trusts pointed out that access to skilled personnel would in any case be the limiting factor.

With the pandemic taking a considerably milder turn than had been envisaged in the scenarios, the need for intensive care places was kept at a level that did not pose a challenge to the hospitals. A total of 1 300 patients were admitted with influenza A in the period between September 2009 to January 2010. Of these, 172 patients were taken into intensive care.

Several specialist communities have queried whether the planned scenarios were realistic. DSB considers that dimensioning of preparedness at the hospitals is a complex issue, and clear guidelines for what the hospitals need to plan for have been requested by several professional groups. An important follow-up task will be to complete the Norwegian Directorate of Health's guideline to pandemic planning in the specialist health services, as well as revising the Pandemic plan to clarify instructions for preparedness capacity at the hospitals.

OTHER FUNCTIONS OF IMPORTANCE TO SOCIETY

A pandemic influenza may cause a large proportion of the population to fall ill simultaneously, and an even larger proportion to stay away from work. Absences may be due to people's own illness, responsibility for others or fear of infection, and may cause huge problems to several sectors. Important functions in society, which the health services also depend on, can be severely impaired or collapse. To face this challenge, the Norwegian Directorate of Health set up a plan support secretariat in cooperation with DSB, for the purpose of providing support to players on the central, regional and local level in their planning and preparedness work.

DSB is not qualified to evaluate how well Norway was in fact prepared for a possibly high degree of absence from the workplace when the main wave of the pandemic broke over the country in October 2009. A more serious pandemic will still be able to pose a huge challenge to activities in all sectors. It is therefore important to carry on planning work to preserve continuity in production in the event that absences will affect a large part of the workplace.

COMMUNICATION

The Norwegian Directorate of Health and Norwegian Institute of Public Health worked closely together on communication related to the pandemic. The communication strategy was based on the Pandemic plan, with clear targets and target groups. The first stage of the communication drive was mainly focussed on hygiene issues, whereas vaccination was a central topic in the later stages. Different means of communication were used to reach the public, such as press conferences and briefings, TV ads and announcements in other media, posters, brochures and information posted on the Internet.

The pandemic was the biggest news item in 2009, and the media storm caused considerable pressure along the way. Surveys have shown that the population to a large degree was satisfied with the information from the authorities, but that a majority began to think that the danger involved in the pandemic was exaggerated. The scepticism against the vaccine was fairly low in Norway compared with other countries. User surveys of the main websites *pandemic.no* and *fhi.no* returned largely positive results.

DSB is of the impression that on the whole the health authorities fulfilled the targets they had expressed in the Pandemic plan. The Norwegian Directorate of Health and Norwegian Institute of Public Health succeeded in their communication drive, and the challenges along the way were dealt with proactively, which meant that the message was communicated well both to health personnel and the population at large. The impression is that the population to a large degree received information which was both consistent and credible.

The first press conference on 27 April meant that the authorities backed up and reinforced the picture which was already being painted in the media, i.e. that the country was facing a potentially serious crisis. DSB is of the view that this was not a pre-arranged strategy on part of the authorities, but rather the result of inadequate coordination in this case. The DSB considers that the worst case scenario was given too much emphasis in the presentation at the press conference, and that it was also presented in a fairly unfortunate manner. At later press conferences, briefings and media communication work in general, the message that the influenza most likely would turn out to be mild, came across in a much clearer way.

HANDLING AT THE REGIONAL AND LOCAL LEVEL

CONTROL, PLANNING AND COORDINATION

The County Governors have a coordinating function on a regional level in times of crises and in peacetime. In addition, the Act relating to control of communicable diseases instructs the County Governors to draw up a preparedness plan for their respective counties. The County Governors played an important part when it came to controlling whether the municipalities had an updated master plan for how to handle the pandemic. The Norwegian Directorate of Health and the County Governors stayed in close contact during the handling period, whereas the dialogue between the County Governors and the Norwegian Institute of Public Health was very limited. In connection with the vaccination, the dialogue mainly took place between the Norwegian Institute of Public Health and the municipalities.

As part of the coordination efforts, the County Governors received updated reports weekly from the municipalities on the current development of the pandemic handling, put them together and submitted a report to the Norwegian Directorate of Health. The Directorate in turn reported to the Ministry. Even though both the County Governors and the municipalities understood the importance of reporting, both levels expressed that they found the reporting regime to be too extensive.

DSB is of the impression that the municipalities were relatively pleased with the information from the central authorities in connection with the handling of the pandemic, but that there were aspects of the information that did not work as well. The sheer volume of information became too much, and the same information would arrive through different channels as well as from different places. The information from the various authorities was not always well coordinated. As mentioned above, there was some dissatisfaction with the information about distribution of vaccines.

Surveys show that the County Governors felt that the pandemic was handled generally well in their own counties, and that the municipalities likewise felt the handling was good in their own municipality. The County Governors and municipalities also considered the national handling as fairly good, but not as

good as the handling in their own counties and municipalities. A large majority of the municipalities felt there was a good balance between central instructions and local freedom in the handling of the pandemic.

The regional health authorities and the health trusts have a duty to draw up emergency preparedness plans for the health services for which they are responsible. The regional health authorities and the health trusts play a central role in the handling of the pandemic with regard to diagnosing and treating the sick, mobilising and organising health personnel as well as vaccination of both patients and health workers. Reporting took place from the health enterprise to the regional health enterprise, which in turn reported to the Norwegian Directorate of Health.

VACCINATION

Vaccination was the activity that received the most attention and required most resources in the municipalities during the response to the pandemic. It started off with vaccination of risk groups and health workers, and proceeded to mass vaccinations. Both the County Governors and the municipalities have expressed that the municipalities in general handled the vaccinations well, and that the vaccination work was largely characterised by everyone pitching in and working together.

All the same, the municipalities did encounter some challenges, partly as a result of the interface with the health authorities and partly due to local conditions. Some of these challenges concerned identifying risk groups, distribution of vaccines, the role of the GPs and the pricing of the vaccines, as mentioned above.

In practice, the risk groups were identified in different ways. In some municipalities the risk groups were identified, called in and vaccinated by the GPs. In other municipalities the practice was that risk groups were to meet for vaccination on their own initiative following announcements in the press. This being the practice, it was inevitable that some people would wrongly claim to belong to a risk group, especially in the first stage of the vaccination process. In some municipalities this caused some concern in connection with the practical implementation.

Based on the above, it would be better to set up a system in which the prioritised groups could be identified in a more uniform way in the municipalities. This would probably mean involving the GPs more in all the municipalities.

The use of GPs in the vaccination process varied considerably between the municipalities. In some local municipalities, they participated both in the vaccination of the risk groups as well as in the mass vaccination, in others only in the vaccination of risk groups and in some municipalities they played no part in the vaccination process at all. Some municipalities have pointed out that communication with the GPs represented a challenge in connection with the vaccination process. There is a clear need to specify the role of the GPs as part of the municipal health services, and to clarify their role in connection with vaccination in future pandemics.

Many of the municipalities, especially the smaller ones, only have a chief municipal medical officer or disease control physician in part-time employment, or none at all. This represents a challenge as these functions are in practice often in charge of the master plans and of starting up the vaccination programmes. There should be an evaluation of how this vulnerability could be reduced in the municipal health service in the event of a new pandemic. Intermunicipal cooperation and a more active role to play for the County Governors would be possible alternatives.

The Norwegian Institute of Public Health estimates that approx. 45 per cent of the population was vaccinated against the new Influenza A virus. Vaccination coverage was highest in the Western part of Norway and the counties from Northern Trøndelag and further north. The lowest vaccination coverage was in Oslo and the Southern counties including Telemark. It is a consistent feature that higher proportions of the population were vaccinated in small municipalities than in the larger ones, which in part is due to the fact that the municipalities in the districts had quite good access to the vaccines at an early stage, when the motivation for vaccination was high. In general, fewer young people took the vaccine compared with the rest of the population. Another characteristic is that fewer men than women had the vaccination.

TREATMENT

The primary health care services received a high number of consultation requests as a result of the pandemic. These services are the first line for receipt of sick people, and thus experienced some challenges in connection with sampling and diagnosing, prescription of medicines, advisory services and

passing information on to the specialist health services. The primary health care services faced further challenges when the disease peaked at the same time as the vaccination programme got underway.

The GPs also played an important part, in connection with treatment and diagnosing patients, and many places also in connection with the vaccination. The GPs' lines of communication to the chief municipal medical officer as well as to the regional and national health authorities do however represent a real challenge which we feel it is vital to sort out.

The primary health care services, particularly in the smaller municipalities are, together with the local hospitals, probably the most vulnerable part of the health sector. In the event of a serious pandemic we face the possibility that the health services in some areas might be unable to function in practice for a shorter or longer period of time.

In connection with the preparations to receive the main influx of people sick with the influenza, the decision was made nationally to acquire 393 new respirators and a lot of other new equipment.

Several of the health trusts have queried why no separate national guidelines were drawn up for intensive care, and no formal lines of communication were established to exchange experiences on treatment of patients with serious complications. In addition, several of the health trusts would have wanted a better functioning sharing of intensive care patients between the hospitals. The lack of isolation wards would have represented a major challenge in some places had the influx of patients been higher.

In DSB's opinion, there is a need for a more precise definition of the hospitals' expected preparedness capacity. In a more severe pandemic, the lack of qualified health personnel could have been a problem.

The allocation of extra resources such as students, the civil defence and personnel from the NGOs, could have been a problem in an emergency situation as it has not been made clear who would have the authority over the use of these resources.

In our opinion there is a major need to formalise, coordinate and integrate the need for extra health personnel in the specialist health services. This must also be coordinated and integrated in collaboration with the municipal health services, as the two services have based their master plans on the same extra personnel resources.

CONCLUSION – LESSONS LEARNED

Overall, Norway was well prepared for the 2009 pandemic. The national emergency preparedness plan for pandemic influenza was last revised in 2006, and in 2008 an agreement had been entered into with GSK on supply of vaccines in the event of an outbreak in the next three years. Also, a series of drills had been carried out on the national, regional and local level.

However, the preparations made were based on the view that the most serious potential risk would be in relation to a pandemic caused by an avian influenza A virus (H5N1), which would have developed characteristics that meant it could also infect people. Mortality would be high for those infected. Contagion between people might be the next step in the development, and able to cause a pandemic with grave results for the world community.

When the news about the outbreak of influenza in Mexico and the US came on 24 April 2009, it was only natural and understandable that the health authorities used their Pandemic plan as a starting point as well as the preparations they had made for a possible outbreak of avian flu. Much of what took place over the first few days must be seen on this basis, such as e.g. the press conference on 27 April, where, as previously stated, a presentation made for use at meetings and seminars on the Pandemic plan was used as a basis.

It is DSB's opinion that NIPH's evaluations should have played a more central place in the handling and communication in that first period. From the beginning, however, it was clear that the outbreak in the USA and Mexico was caused by an entirely different virus than the one that had been considered to be most likely when the Pandemic plan was drawn up. The NIH which is the national disease control experts and the foremost professional body in the country with regard to epidemiology, at once began the task of analysing the information available from Mexico, the USA and Canada, and as early as that first week-end assessed that it was most probable that the influenza would turn out to be a mild type of pandemic with low lethality.

The uncertainty of those first few days may serve to illustrate the inherent problem with having preparedness plans that have been produced with a particular scenario in mind. People could easily react based on the preconditions of the plan and not according to the prevailing circumstances in the actual situation. The worst-case scenario in the pandemic plan became a decisive factor for much of the planning in the first months, even though it was clear at an early stage that this scenario was unlikely.

However, the actual situation was handled based on analysis of current developments throughout. This meant that the use

of policy instruments was in line with the postulations in the Pandemic plan to the effect «[m]easures must be adjusted to suit the situation at any given time, and must not exceed such efforts as are deemed to be necessary.» (National pandemic influenza preparedness plan, version 3.0, 16 February 2006, MHCS, p. 89).

The Norwegian Directorate of Health headed and coordinated the handling of the situation based on the delegation of authority from the Ministry of Health and Care Services, in accordance with the *Comprehensive national health and social preparedness plan* and based on the provisions in the communicable diseases Act. The County Governors played an important role together with the regional health authorities as a channel of communication and reporting towards the health services. On the national level, the Norwegian Institute of Public Health constituted a key support.

The special preparedness organisation in the health sector passed the test, but issues also came to light that would have caused problems had the situation been more serious. One such issue is for example how far the authority of the Norwegian Directorate of Health extends in areas where legislation has given other parties a role or responsibility. In this specific situation, these issues were highlighted first and foremost in relation to the Norwegian Institute of Public Health with regard to vaccinations.

The Norwegian Directorate of Health's crisis management and organisation should, in our opinion, aim for a more distinct division between the operative, analytical and strategic tasks. Reference is here made to the Storting report no. 37 (2004-2005) *The tsunami disaster in South Asia and central crisis management*, Ch. 7.1. Furthermore, the internal processes in the Directorate and between the Directorate and other Parties (such as e.g. MHCS) should be better documented.

It is also important to be aware that the relationship between the key parties; the MHCS, the Norwegian Directorate of Health and the NIPH, can actually be *too close*, and that as a result, roles and processes might tend to overlap. There is a risk that one might lose the quality assurance aspect of keeping up distinct barriers between roles and functions. It is DSB's view that the process that led to a decision to recommend vaccination of the whole population could serve as an example of this.

The handling of the vaccination advice showed that the key parties have a different understanding of where responsibilities formally rest. It is also somewhat unclear how the decision of a mass vaccination actually was made, and which evaluations it was in fact based on.

In DSB's view there would seem to be cause for distinguishing more clearly between the roles of the Norwegian Directorate of Health and the Norwegian Institute of Public Health. The professional assessments made by the Norwegian Institute of Public Health should be given more weight than was the case in the early phase of events, whereas the Norwegian Directorate of Health's responsibility for the coordination and implementation of measures should be made more specific.

The Norwegian health authorities took a proactive stance towards the pandemic. This is seen by the way they always factored in the possibility of a far more serious scenario than the most likely one. DSB is of the opinion that this is a correct strategy, and one that would have made it easier to respond to an unanticipated negative turn of events than had one settled for a more passive attitude. However, as a consequence, it may be that the use of resources, seen in hindsight, was unnecessarily high, and that the population was given the impression that the situation was more serious than the authorities actually believed it to be.

Despite the proactive attitude, it may seem that the parties involved became aware of essential issues somewhat late in the day. This would apply to questions such as what was needed to provide intensive care of seriously ill patients and measures to take pressure off the GPs.

The Norwegian Directorate of Health and Norwegian Institute of Public Health have their own separate communication channels to the health services. This might represent a challenge, especially because important links in the chain such as the County Governors were not included in this flow of information.

The County Governors played an important role in the general regional and local handling of the pandemic, as DSB see it. The County Governors are part of the directorate's management and reporting system. DSB is of the view that they should also be given a role in coordinating the response work in the municipalities and deploying the additional personnel resources such as students and others, and that they could also have contributed to ensuring that the distribution of the vaccines took place in a more practical and flexible manner.

The Act relating to control of communicable diseases should also be reviewed, in the opinion of the DSB, with a purpose of clarifying the respective roles of the Norwegian Directorate of Health, Norwegian Institute of Public Health and the County Governors. It might also be a good idea to evaluate other aspects of the Act, such as whether it is sufficiently flexible to serve as an appropriate tool in the case of a mild or moderate pandemic.

The municipalities' most demanding task in connection with the pandemic was the vaccination activities; of health personnel first and then risk groups, followed by the population at large. The municipalities were in practice left to organise this vaccination effort as they saw fit. The surveys conducted of the County Governors and in the municipalities reflect a large degree of satisfaction with how the vaccinations were handled locally.

On the other hand, the patients' organisations received a number of complaints from their members who reported a poor and haphazard organisation, people jumping the queues and such like. It is hard to say how representative this picture is. The DSB would like to point out, however, that during the pandemic there was no joint and uniform system to identify those that were in the priority risk groups and how they should be treated.

This is an example of an issue that should have been thought through in advance and incorporated into the Pandemic plan. There are many other such examples to show that, despite many years of efforts, the preparations had not been thorough enough to discover and address challenges that turned out to be important when the pandemic struck. This might be because planning had not sufficiently involved those levels of the health services that would be handling the problems in practice.

The primary health care services probably constitute the most vulnerable part of the national pandemic preparedness organisation. This is because many of the municipalities in Norway are small - and some of them very small indeed. Had the picture been anything like the one that was outlined in the worst-case scenario of the Pandemic plan, there is a risk that the primary health care services would have completely collapsed in some places, for a longer or shorter period of time. In fact, in this pandemic, the smaller municipalities actually had an advantage. They obtained better vaccination coverage at an early stage, and did not have any problems in identifying their risk groups.

As regards communications, the handling of the pandemic appeared to a large degree as successful. Following an unfortunate start, the work was carried out in a determined way which inspired confidence. However, the DSB feels that, especially after the summer, the efforts should have been differentiated towards the various target groups to a far larger extent, and that there should have been higher awareness of how networks and social media could be used for communication purposes.

Chapter 6.1 describes the criteria used for weighting discoveries made in this review.

The criteria for good handling practices would be if they contributed to:

- reducing the number of sick people
- reducing the number of seriously sick people and fatalities
- maintaining important functions in society
- not causing *unnecessary* unrest in society and individuals
- efficient use of society's resources

Norway had more people taken ill and slightly higher mortality rates during the pandemic than most of our neighbouring countries. This has been explained with Norway being hit by the main wave somewhat earlier than the other Nordic countries, and that the vaccination did not therefore have the full effect in this country. It is difficult to assess whether this is correct, or whether there were other causes behind these differences. However, the DSB has not found, or been presented with, any shortcomings on the part of the response from the authorities that might have caused Norway to have higher sickness and mortality rates than what might have been the case otherwise.

The 2009 pandemic did not take on a scale that might have threatened important functions in society. With the exception of the planning efforts in the first few months, this was not a relevant issue when it comes to the way the efforts were handled centrally either.

DSB sees that there were two aspects of the way in which we handled the pandemic that might have led to more worries in the population than necessary. Firstly, there was the first press conference (27 April) which may have served to reinforce the exaggerated picture the media was already painting of the seriousness of the situation. At a later stage, the way the vaccinations of the risk-exposed groups were organised gave rise to worries and anxiety in certain circles.

The most difficult question to answer is whether the health authorities could have achieved the same results through a more efficient use of resources. In hindsight, one might query whether the acquisition of respirators and other equipment was exaggerated, and whether the preparedness level was kept artificially high in the specialist health services for too long. In the light of the uncertainty connected with future developments at the time these decisions had to be made, the picture might look entirely different. However, the DSB feels that there is reason to ask whether the scenarios the planning was based on could have been further scaled down in September.

The fact that planning in the period May – August had to be based on the worst-case scenario in the Pandemic plan, whereas it was known quite early on that this was very unlikely, might likewise have led to a loss of efficiency. The fact that there was a reassessment of this in the first plan scenario which

was presented on the 29 July was a good thing, but it would have been even better if downscaling had taken place at an earlier stage.

Efficient use of resources is also connected to efficient organisation. The DSB believes that the division of roles between the Norwegian Directorate of Health and the Norwegian Institute of Public Health could have been clearer, but we do not believe that this matter considerably reduced efficiency. However, the distribution of the vaccines and the vaccination programme could probably have been executed in a more efficient manner. A distribution strategy based on larger overall supplies to the municipalities would have entailed reduced use of resources in the vaccination efforts, but would also have caused a delay in vaccinations of those who needed it the most, with the possible consequences this might have had for the number of severely ill people and the total number of fatalities.

Most of the weaknesses described in this report, however, were of little or no importance for the outcome of the response in our assessment. The reason it might still be important to point them out is that they represent areas of vulnerability that might cause problems in a more demanding situation, and it is therefore recommended that we learn from them.

WHICH CHALLENGES WOULD NORWAY HAVE FACED IN A WORST-CASE SCENARIO?

The worst-case scenario in the National preparedness plan for pandemic influenza is based on the Spanish influenza epidemic in 1918-19. The scenario stipulates that 50 per cent of the population will be taken sick and be bedridden. The excess mortality is estimated to be somewhere in the region of 0.4 per cent and 1.1 per cent of the sick, which would result in an extra 5 000 to 13 000 deaths compared to a normal winter season.

The National vulnerability and preparedness report (NSBR) from 2008 includes calculations that prove that at the peak of such a scenario as much as 40 percent of the workforce might be absent due to illness.

The experience from the pandemic of 2009 shows that the time of year of an outbreak might be of significant importance with regard to the ability to acquire vaccines before the sickness strikes the country. The new influenza A (H1N1) occurred at a favourable point of time from our perspective, as the influenza season in the northern hemisphere was waning. On the southern hemisphere, the timing of the outbreak was correspondingly unfortunate, and was therefore hit by the main wave long before the vaccines had been produced.

In a future outbreak of severe pandemic influenza we cannot expect to be equally fortunate when it comes to the timing. Should the outbreak come at a more unfortunate point in time, the general response efforts and use of antiviral drugs will become significantly more important than they were this time. There is also reason to underline that we cannot rely on Tamiflu and other antiviral drugs having an effect on a future aggressive pandemic virus.

A worst-case scenario would represent huge challenges for the primary health care and specialist health care services alike, especially if there is no vaccine available when the main wave hits. There is a limited number of intensive care beds in the hospitals, and even though these could be increased by using alternative methods and maximising the use of capacity in the regional health authorities, we are unlikely to be able to offer fully satisfactory services to all those who would need it.

The capacity at our laboratories could turn out to be another bottleneck. The pandemic of 2009 caused many laboratories to be overworked.

A pandemic as described in the worst-case scenario would have represented a huge challenge for the smaller hospitals in particular, because these are naturally more vulnerable to loss of personnel and have fewer resources to redeploy.

Also the primary health care services including GPs and pharmacies would have to expect significant challenges in the event of a grave influenza epidemic. Here too, the smaller units would be particularly vulnerable. Based on the current regulations, the County Governors would not necessarily have been able to direct resources to municipalities and areas with special needs.

It is not inconceivable that the health services in certain areas would be practically non-functioning either fully or partially.

NSBR 2008 describes the potential consequences of a worst-case scenario for several sectors. The 2009 pandemic was not of a scale to put the continuity of operations in critical public functions at stake. Should a similar situation be met with prophylactic use of antiviral drugs to, and vaccination of, key personnel we would face quite a challenge however, as there is currently no national summary of what functions should be considered critical for society and what operations are particularly important to keep going.

As mentioned above, in the next pandemic, Norway cannot expect to be able to secure vaccines before the main wave hits

the country. Should vaccines turn out to be available, the lack of systems for identification of people in the risk groups would represent considerable challenges. The disease in itself would cause much worry and distress, but these sentiments would be reinforced if the government were unable to ensure that priority groups were vaccinated first.

The 2009 pandemic shows that the division of responsibility between the central players in a situation such as this has not been sufficiently clarified. In addition, the low degree of formalization of authorities and cooperation aspects represent another weakness. The same applies to the lack of coordination of the communication between the central and regional sectors. In a long-term and unmanageable situation, such factors might have caused misunderstandings and conflicts which would have contributed to reducing the efficiency of the response both centrally and in the health services.

DSB believes that it is important for Norway to reinforce its pandemic preparedness further. Even though the last pandemic event took place 30 to 40 years ago, the likelihood of another breakout next year is no lower than it was in 2008. The avian influenza A virus (H5N1) continues to be a threat, and we may see yet other viruses developing the ability to spread between people.

DSB's RECOMMENDATIONS

Based on the issues identified in our review of the response to the pandemic, the DSB presents the following recommendations:

- a. The description of the authority invested in the Norwegian Directorate of Health when delegated by the Ministry of Health and Care Services to handle an event should be made more specific. This can be included in the *Comprehensive national health and social preparedness plan* or in each case as required.
- b. In future, delegation of authority based on the Comprehensive plan should be formalized to ensure that all the involved entities have a clear and unambiguous understanding of what such delegation entails.
- c. An assessment should be made of which mechanisms might simplify coordination across all involved sectors in the management at agency level (in this case between the Norwegian Directorate of Health and agencies/authorities in other sectors).

- d. The roles of the Norwegian Directorate of Health and the Norwegian Institute of Public Health as an administrative entity and a specialist entity respectively, should be specified more clearly.
- e. A demarcation should be implemented between the Norwegian Directorate of Health and the Norwegian Institute of Public Health with regard to their areas of responsibility for vaccines/vaccinations.
- f. For crisis management in the health sector, the Norwegian Directorate of Health should consider setting up a formal, superordinate forum for meetings where also the other important entities will participate.
- g. The Norwegian Directorate of Health should also consider introducing a more distinct delineation between the operative, analytical and strategic roles internally, e.g. through a separate crisis organisation.
- h. Norwegian Directorate of Health and the NIPH's lines of communication to the regional and local level should be managed better in an emergency situation. The Norwegian Institute of Public Health should attend meetings/ telephone conferences with the County Governors and the regional health authorities.
- i. An assessment should be made of whether it is possible to simplify the situation report lines between the various entities both horizontally and vertically to obtain a better overview, by making use of e.g. Internet solutions.
- j. The central authorities should cooperate to prevent the reporting load of the County Governors and the municipalities from becoming heavier than necessary.
- k. The GP's role as part of the primary health care service in the municipalities must be made clear, and laid down in law. The communication line between the Health Directorate – County Governor -chief municipal medical officer – general practitioners– must be set up and reviewed.
- l. The role of the Pandemic committee as an advisory body to the MHCS in connection with crisis management should be further assessed.
- m. The Act relating to control of communicable diseases should be reviewed on the basis of lessons learned from the pandemic. The County Governor's role with regard to communicable diseases should be reviewed and clarified. The rules regarding delegation of authority must be reviewed to achieve clarity and flexibility.
- n. The health authorities should use the experience from the management of the 2009 pandemic as a basis for their future pandemic vaccine agreements. Acquisition of pre-pandemic vaccines based on the avian influenza A virus (H5N1) should still be considered.
- o. In the event of future pandemics, the plan scenarios should be prepared at an earlier stage and be revised at regular intervals.
- p. The reporting systems for communicable diseases should be developed to enable a speedier and more differentiated geographical information flow.
- q. The cost/benefit aspect of mass vaccinations should be subject to further analysis.
- r. The distribution methods for the pandemic vaccines should be looked into further, especially with a view to achieving higher robustness, flexibility and predictability by using existing logistic systems and regional distribution channels and by giving the County Governors a coordinating role.
- s. The national pandemic plan must be revised. The capacity of intensive care units and laboratories must be given a more prominent position in the plan. The central health authorities must be clear when stating what they expect from the health trusts with regard to treatment capacity in a pandemic.
- t. A pandemic intensive register must be ready before the outbreak of the next pandemic.
- u. National guidelines should be drawn up, with a description of which societal functions are the most critical and which tasks must continue operation during a pandemic or other crisis situations.
- v. An assessment should be made of how to identify people in the risk groups in a pandemic. A system for extracting patients' medical records might be one of several possible solutions.

- w. The Norwegian Directorate of Health and the Norwegian Institute of Public Health should assess how , in a future crisis, it would be possible, to increase the use of channels and methods that would open for a dialogue with affected groups.
- x. The vulnerability of the primary health care services and how to mitigate this should be discussed. Cooperation between municipalities would be one of several possible options. The County Governor should be enabled to direct the resources between the municipalities and vis-à-vis the specialist health services in a crisis.
- y. In a future pandemic, the price of vaccination should be fixed and the same for everyone, all over the country, and regardless of how the vaccination programme is organised in each municipality. This price should be determined at an early stage of the planning process, and it is important to evaluate the price level against the desired coverage.

REPORT

P.O. Box 2014
3103 Tønsberg

Tel.: +47 33 41 25 00
Fax: +47 33 31 06 60

postmottak@dsb.no
www.dsb.no

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