



Die
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regieren

Information provided to patients about measles vaccinations in general practices (GP)

Analysis of the information provided to patients about
adult measles vaccinations in GP practices

wirksam regieren division at the Federal Chancellery
on behalf of the Federal Ministry of Health (BMG)



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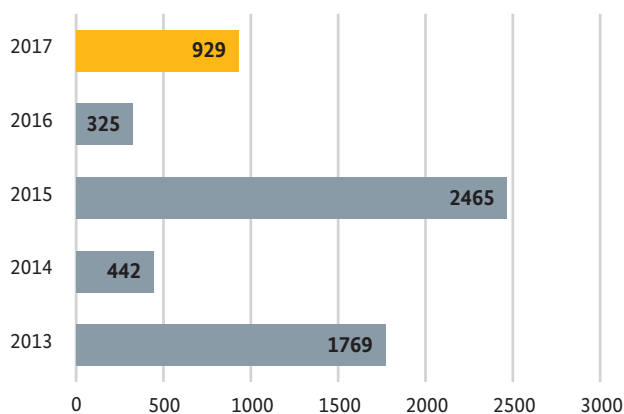
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Executive summary

Measles is a highly contagious viral illness. For infants, children and young people in particular, but also for adults, it can have serious and even fatal consequences. The only effective protection against measles is vaccination.¹ According to estimates by the World Health Organization (WHO), an expansion of global vaccination programmes between 2000 and 2016 reduced measles mortality by 84% and prevented the deaths of over 20.4 million people.²

Vaccination offers not only protection, but the potential to eliminate measles altogether. The WHO therefore set itself the goal of eliminating measles in Europe by 2015 and worldwide by 2020.³ In some countries in Europe, such as Finland, this goal has already been reached through the consistent implementation of vaccination programmes. In Germany, a sufficient vaccination rate has not yet been achieved. This is evident from the repeated outbreaks of measles in recent years. According to the Robert Koch Institute - Federal Institute for Infectious and Non-communicable Diseases (RKI), 929 people contracted measles in Germany in 2017.⁴ This means that the level of fewer than 80 cases of measles per year called for by the WHO was exceeded significantly in Germany.⁵

Figure 1: Cases of measles per year in Germany 2013 to 2017



The Federal Government has therefore pledged to eliminate measles in its *National Action Plan for the Elimination of Measles and Rubella in Germany 2015 - 2020*.⁶ To achieve this goal, the immunity of the population in all age groups must reach at least 95%.⁷ This phenomenon is known as herd immunity.

In Germany, immunity against measles varies considerably by age group and region. There is a significant immunity gap among adults born after 1970.⁸ This is partly due to the fact that, up until 1990, it was believed that *one* vaccination was sufficient. Studies show, however, that *two* vaccinations are needed to ensure immunity. The Standing Committee on Vaccination (STIKO) has therefore recommended a booster vaccination for adults born after 1970 if they have only received one vaccination for measles or their vaccination status is uncertain.⁹

However, only a few adults in this age group are familiar with the latest vaccination recommendations: In a 2014 survey by the Federal Centre for Health Education (BZgA), only around a quarter of those questioned said they were aware of the recommendations regarding measles vaccinations for adults born after 1970 which had been in place since July 2010. Adults in this age group who were not fully vaccinated most commonly cited the following three reasons for this:¹⁰

- 1 60% stated they did not know they needed a measles vaccination
- 2 25% were concerned about possible side effects of the measles vaccine and
- 3 19% assumed that measles was not a particularly serious disease.

In light of these findings, the *National Action Plan for the Elimination of Measles and Rubella in Germany 2015 - 2020* recommends targeted education about measles and measles vaccination among adults born after 1970.¹¹

To investigate how the knowledge gap surrounding measles and measles vaccinations in this age group can be closed, the Federal Ministry of Health (BMG) commissioned the *wirksam regieren* division to carry out two randomised controlled studies. Both studies were carried out in the fourth quarter of 2016.¹² This is the second of these studies.

The starting point of the study is the personal provision of information to patients by their GP. Studies reveal that a consultation in the context of a trusting doctor-patient relationship encourages an informed decision regarding vaccination.¹³ It is unclear to what extent GP practices already respond in a targeted manner to their patients' existing vaccination gaps and offer personalised consultations.

For this study, GPs were therefore asked in a letter from the Federal Ministry of Health to inform their patients personally about the vaccination recommendations in place since 2010 and to educate them on the risks of measles and the measles vaccine. A portion of the GPs were also asked to put out patient leaflets in the waiting room or to have them handed out personally at reception. The study examined whether these measures are sufficient to close the knowledge gap among adults born after 1970 and increase the number of vaccinations following education by the doctor.

The study was carried out in cooperation with the BZgA, the RKI and several Allgemeine Ortskrankenkasse (AOK) health insurance providers as well as the AOK Federal Association in around 4,000 GP practices.

Compared with a control group which had not received any letter, a slightly higher number of vaccinations was observed in the practices that had been contacted. In view of considerable regional variations, this result cannot be demonstrably attributed to the letter, however.

This does not mean that a GP personally providing information to the patient cannot make a contribution to closing the vaccination gap around measles. The results do show, however, that a written request from the Federal Ministry of Health to doctors to offer more consultations on this topic had no demonstrable impact on the number of vaccinations. Possible explanations for this include the fact that, despite the request, the GP practices did not carry out any additional consultations because they assumed that all patients had already been sufficiently informed, because they did not have time for it in their everyday practice operations or because the letter did not receive sufficient attention given the considerable number of letters received by GP practices.

In comparison, a parallel study by the *wirksam regieren* division found that direct information to the patient in the form of a letter from a health insurance company did have a demonstrable effect on the closure of the measles vaccination gap in adults.¹⁴ In this case, through direct information to patients, the number of vaccinations increased from 3 to 8 per 1,000 adults. This means that the number of vaccinations was demonstrably more than doubled as a result of information being sent directly to patients.

The results of both studies illustrate that the various measures differ considerably in their effectiveness. A comparison of the two studies has been published on the website www.bundesregierung.de/wirksam-regieren. They demonstrate the contribution that impact analyses can make to project planning. Early impact analyses of alternative actions can allow effective measures to be identified and evidence-based actions to be taken.

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I. Research Question

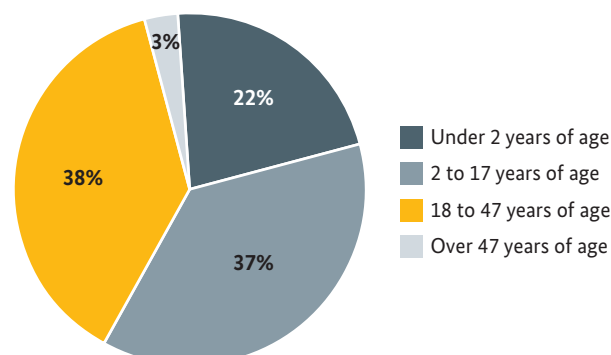
Since 1984, the member states of the European Region of the World Health Organization (WHO) have been striving to eliminate measles. For Germany, the level required by the WHO of one case of measles per million inhabitants per year would mean a maximum of 80 cases of measles occurring annually. So far, this target has not been achieved. 929 cases of measles were recorded in Germany in 2017.¹⁵

In order to prevent endemic virus transmissions and to permanently reduce the number of cases of measles, at least 95% of the population must be immune to the disease. At this level, so-called herd immunity would be achieved. This is the only way to protect infants and people with weakened immune systems who cannot be effectively vaccinated against measles themselves.

Until 1990, it was assumed that *one* measles vaccination was sufficient to establish long-term immunity. Studies show, however, that *two* vaccinations are needed to ensure immunity. Since 1991, STIKO has therefore recommended a second vaccination against measles for children and young people. According to these recommendations, the first vaccination should be given at the age of 11 - 14 months and the second at the age of 15 - 23 months. Since 2010, STIKO has also recommended that adults born after 1970 who have only received one measles vaccination or whose vaccination status is unknown receive a booster vaccination.¹⁶ This recommendation has been made partly because the immunisation of this age group is essential for the establishment of herd immunity. This recommendation has also been made on the basis of the higher complication rates associated with measles in adults, such as lung, middle ear and brain inflammation.¹⁷

In 2017, 38% of measles cases involved adults born after 1970¹⁸ (cf. Fig. 2 – 18 to 47-year-old group). This indicates a significant immunity gap in this age group.

Figure 2: Cases of measles in 2017 by age in percent¹⁹



In Germany, vaccinations are not recorded in a vaccination registry. As a result, vaccination rates can only be estimated. This is done using small surveys and analyses of billing data from health insurance providers. It is currently assumed that the rate of measles vaccinations among 18 to 29-year-olds is around 80%. Among 30 to 39-year-olds it is only around 47%, however, and just 25% among 40 to 49-year-olds.²⁰ These figures refer to the administration of at least one dose of the measles vaccine. There is no information available regarding what proportion of these individuals have received a second dose.

Gender-specific differences are also observed in the vaccination rates. Generally speaking, and also specifically for measles, women tend to have higher vaccination rates than men.²¹

In a survey by the BZgA, only around a quarter of those questioned stated that they were aware of the recommendations in place since July 2010 for measles vaccinations for adults born after 1970, advising two vaccinations.²² Accordingly, it can be assumed that the number of people who have received two doses of the vaccine is significantly lower than the number who have received one dose.

The survey by the BZgA highlights the three most important obstacles to vaccination among adults born after 1970 who are only partially vaccinated:

- 1 60% stated they did not know they needed a measles vaccination
- 2 25% were concerned about possible side effects of the measles vaccine and
- 3 19% assumed that measles was not a particularly serious disease.

Given the knowledge gaps that exist in relation to measles and the measles vaccination in adults, the *National Action Plan for the Elimination of Measles and Rubella in Germany 2015 - 2020* set out by the Federal Government recommends targeted education for adults born after 1970.²³

Scientists are discussing various measures, depending on the reasons for a lack of or incomplete vaccination.²⁴ If there is only a knowledge gap in relation to the current vaccination recommendations, then this can be resolved by providing targeted information to the relevant patient group. Concerns about possible side effects of the measles vaccine are generally more difficult to address. Understandable information and representations of the risks and side effects of the measles *vaccine* can help here.²⁵ The survey by the BZgA also revealed that a significant proportion of partially vaccinated people assumed that measles is not a particularly serious condition. In light of this result, providing education about the actual risks of the measles *disease* for adults appears to be a sensible and important measure. The importance of individual immunity for herd immunity is also new and relevant information for many.

To investigate how the knowledge gap surrounding measles and measles vaccinations in adults born after 1970 can be closed, the BMG commissioned the *Effective Government* Division to carry out two randomised controlled trials. Both trials were carried out in the fourth quarter of 2016. They examine two complementary methods of providing information about vaccination recommendations and the risks of measles and the measles vaccine, and the contribution of this education to closing the vaccination gap.

The first study looked at what contribution information letters sent directly from health insurance providers to their customers can make to closing the knowledge and vaccination gap.²⁶ The results show that, following this direct patient information, the number of vaccinations rose from 3 to 8 per 1,000 adults in the quarter examined. This means that the number of people who received a measles vaccination more than doubled as a result of direct information about the vaccination recommendations.

This study is the second one commissioned. The starting point of the study is the personal provision of information to patients by their GP. Studies reveal that a consultation in the context of a trusting doctor-patient relationship encourages an informed decision regarding vaccination. It is unclear to what extent GP practices already respond in a targeted manner to their patients' existing vaccination gaps and offer personalised consultations. For this study, GPs were therefore asked in a letter from the Federal Ministry of Health to inform their patients personally about the vaccination recommendations in place since 2010 and to educate them on the risks of measles and the measles vaccine.

The study examines whether this measure is suitable to close the knowledge gap and to increase vaccination rates as a result of this education. The study also looked at whether the advice from GPs can be meaningfully supported by providing or handing out informational material in the practice. To help the GPs provide information to their patients, material was provided by the BZgA, along with information leaflets listing the facts about measles and the measles vaccination in adults.



II. study

Behavioural science background

- **Information and advice to patients in the context of the doctor-patient relationship**

When it comes to decisions about health, patients tend to place trust in their GPs. The starting point for this study was therefore the assumption that a consultation in the context of a trusting doctor-patient relationship encourages an informed decision regarding vaccination. Previous studies have shown that the majority of patients attach a great degree of importance to advice from their GP when making a decision regarding vaccination.²⁷ Recent surveys carried out on behalf of the BZgA revealed that over a quarter of those questioned had been given advice regarding vaccinations for adults over the last two years.²⁸ This advice had come almost exclusively from a doctor, usually a GP. Asked about the motivations for vaccination, patients frequently mentioned vaccination advice from their GP in particular. For 42% of those vaccinated, advice or information from their doctor was the motivation for the vaccination.²⁹ These results indicate that information and advice in a GP practice is in principle a suitable method to close the knowledge gap around measles vaccinations in adults and, as a result of this education, to help to close the vaccination gap. In addition, GP practices, by virtue of their central position in patient care, are regarded as ideal disseminators for education on health issues.

The following questions remain unanswered:

- **Is a written request to GPs to specifically inform patients about updated vaccination recommendations a suitable method of closing the knowledge and vaccination gap?**
- **To what extent can information from the GP be supported by also providing or giving out informational material to patients in the GP practice?**

To answer these questions, 3,300 GPs were asked by letter for the purposes of this study to inform their patients about the measles vaccination and in particular to approach patients born after 1970 about their vaccination status in a personalised consultation.

Some of the doctors were also asked to place information brochures on the subject of measles in the waiting room, or to ask receptionists to hand these out to patients in the target group. This yields information on whether these methods conventionally used in GP practices to provide information support the personalised consultation effectively and influence vaccination rates. The vaccination rates of the practices that received letters were then compared with the billing data from a control group of practices that had not received a letter. The allocation of GP practices to the various groups was random. In a fourth group, around 700 doctors were addressed in a personal consultation by a clinical adviser from the health insurance provider regarding education about the measles vaccination for adults. This fourth group could not be assigned randomly. This means that it is not directly comparable with the control group or the other test groups. The results, however, provide initial indications of the impact of a personal appeal to doctors.

- **Easy-to-understand health information and risk communication**

To support GPs in the provision of information and advice, the facts about measles and the measles vaccination in adults were summarised for the doctors in an information sheet (*Figure 3*). It provides current data from the RKI regarding the risks of measles and the possible side effects and risks of a vaccination in an easy-to-understand form. It was intended to assist GPs in their personalised consultations with patients and to help them explain the measles infection and the measles vaccination. The information sheet was developed by *wirksam regieren* in consultation with the RKI.

Key to the ease of comprehension of health-related information is the way in which frequency rates are communicated. This plays a significant role especially when communicating the risks of a disease or treatment. Frequency rates are easier to understand if they are given as natural frequencies, rather than as relative frequencies or percentages.³⁰ This applies both to laypersons and to experts.³¹ Consequently, the frequency rates relating to the side effects of medi-

cines are presented as "1 in 1,000 patients" (natural frequency) instead of "0.1% of patients" (percentage).³² Info box 1 illustrates how specifying natural frequency rates has been considered in the recommendations for the design of packaging inserts in the German Medicinal Products Act (AMG).

During the development of this information sheet, these findings regarding the comprehensibility of frequency data were taken into consideration and the natural frequencies of the risks and side effects of measles and its vaccination were used.

The importance of herd immunity was also explained. Many people are still not aware of the importance of individual immunity for ensuring herd immunity, making this another important piece of information in the context of vaccination decisions.

Information box 1: Natural frequencies increase comprehensibility

Example from the recommendations regarding the design of packaging leaflets as per Section 11 of the AMG for human medicines

Very common: Can affect more than 1 in 10 people

Common: Can affect up to 1 in 10 people

Occasional: Can affect up to 1 in 100 people

Rare: Can affect up to 1 in 1,000 people

Very rare: Can affect up to 1 in 10,000 people

Not known: Frequency cannot be determined based on the data available

The importance of patient-appropriate formulation and the comprehensible presentation of frequencies is reflected in the recommendations for the design of packaging leaflets as per Section 11 of the German Medicinal Products Act (AMG) for human medicines (as per Section 77 Para 1 AMG) and in the requirements of Section 22 Para 7 Sentence 2 of the AMG (reviewing the comprehensibility of packaging leaflets). These implement the EU recommendations from the "Guideline on the Readability of the Labelling and Package Leaflet of Medicinal Products for Human Use".³³

Figure 3: "Measles and the measles vaccination" information sheet for doctors



"Measles and the measles vaccination" information sheet

Isn't measles a childhood illness?

- No. It affects adults too. In 2015, **400 out of 1,000** people who contracted measles in Germany were over the age of 20.

How dangerous is the measles virus for adults?

- In Germany, around **2,500** people contracted measles in 2015. As a result of patchy vaccination, regional outbreaks can occur at any time with a significantly increased risk of infection, as has been seen recently in Berlin.
- Between **10 and 55 in 1,000** people infected with measles will develop inflammation of the lungs and **1 in 1,000** people will develop inflammation of the brain as a result of the infection. This can result in permanent brain damage and can even be fatal.

When should adults be vaccinated?

- For complete immunity, two measles vaccinations are needed, which are usually administered during childhood.
- All adults born after 1970 who were not vaccinated during childhood or who only received one vaccination, or who are unsure of their vaccination status, should get **vaccinated against measles**.

How well does the measles vaccine protect adults?

- **950 out of 1,000** people who have not been vaccinated and who come into contact with the measles virus will be infected. Measles is therefore highly contagious.
- **10 out of 1,000** vaccinated people who come into contact with the measles virus will be infected despite having two vaccinations. Compared to not being vaccinated, the vaccination thus provides highly effective protection.

How serious is the risk of side effects after vaccination for adults?

- **2 to 5 people out of 100** who receive the vaccine will develop a non-infectious measles-like condition, which is generally associated with a mild, measles-like rash and fever, and rarely with joint pain.
- **0 to 1 out of 10,000** people who receive the vaccine will develop allergic reactions or a temporary reduction in their platelet levels, which impairs blood clotting.

What is herd immunity, and why is it important?

- The more people that are vaccinated, the more likely it is that the disease will no longer be able to spread.
- Adults who contract the disease may spread it more easily than young children, as they have contact with more people on average.
- This so-called herd immunity also protects infants and people with weakened immune systems who cannot be effectively vaccinated against measles themselves.
- In the long term, it will be possible to prevent the development of measles infections almost completely; this is a goal that has long since been reached in some parts of the world, including in Europe, and one that we also want to achieve here in Germany with your help.

• Information brochures for patients' own information

Information brochures are a widely used method of communicating information on health matters. They are intended to provide education on key aspects of a subject in an easy-to-understand way. They usually also contain links to further information. Studies show that information brochures generally only have a small effect on the level of knowledge and the behaviour of patients if they are used in isolation. When combined with verbal information or advice, however, they appear to be effective in many cases.³⁴ Scientists therefore recommend using information brochures primarily to supplement the verbal advice given by a doctor.

To test the effect of supporting patient education in this way, some of the GPs in this study were asked to offer their patients information brochures as a supplementary source of information in addition to their personalised consultation. To this end, information brochures from the BZgA were also provided, to be placed in the waiting room for patients to read or to be given to patients at reception. The intention behind placing brochures in the waiting room was to enable patients to use the waiting time to learn about relevant health topics and then to ask their doctor any questions they may have or about treatment options. Handing brochures to patients at reception had a similar purpose. By giving out these brochures at reception, the idea was also to ensure that the relevant patient group was given the correct information and actually engaged with it. By simply placing the brochures in the waiting room, neither of the above points is achieved as information brochures are often overlooked and do not reach the target group. A receptionist giving the brochures out can also help to contextualise the information.

In the study, an information brochure from the BZgA was used which provided information about the measles, mumps and rubella vaccination and which discussed the current STIKO recommendations for adults born after 1970 (for excerpts, see *Figures 4 and 5*, for the full brochure see *reference materials A1*).

Figure 4: Information brochure from the BZgA. Front and back

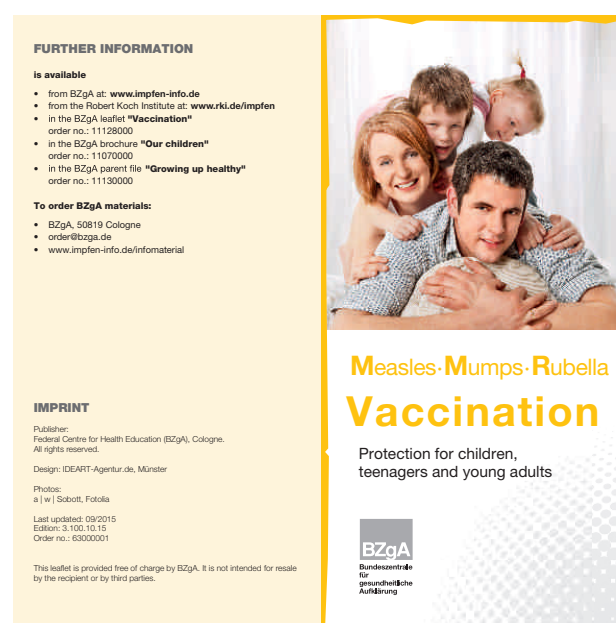


Figure 5: Information brochure from the BZgA. Text excerpt on the measles vaccination recommendations for adults amended in 2010

When is vaccination recommended for adults?

As more and more young adults are contracting the disease, since 2010 STIKO has recommended a booster vaccination against measles for all people born after 1970 who did not receive the vaccination during childhood or who only had one vaccination. The vaccination uses the MMR vaccine.

In particular, parents and young adults working in community facilities or in the health service should have their vaccination status checked. Individuals protected against measles will not, for example, infect infants, who cannot be vaccinated.

Study design

Test groups

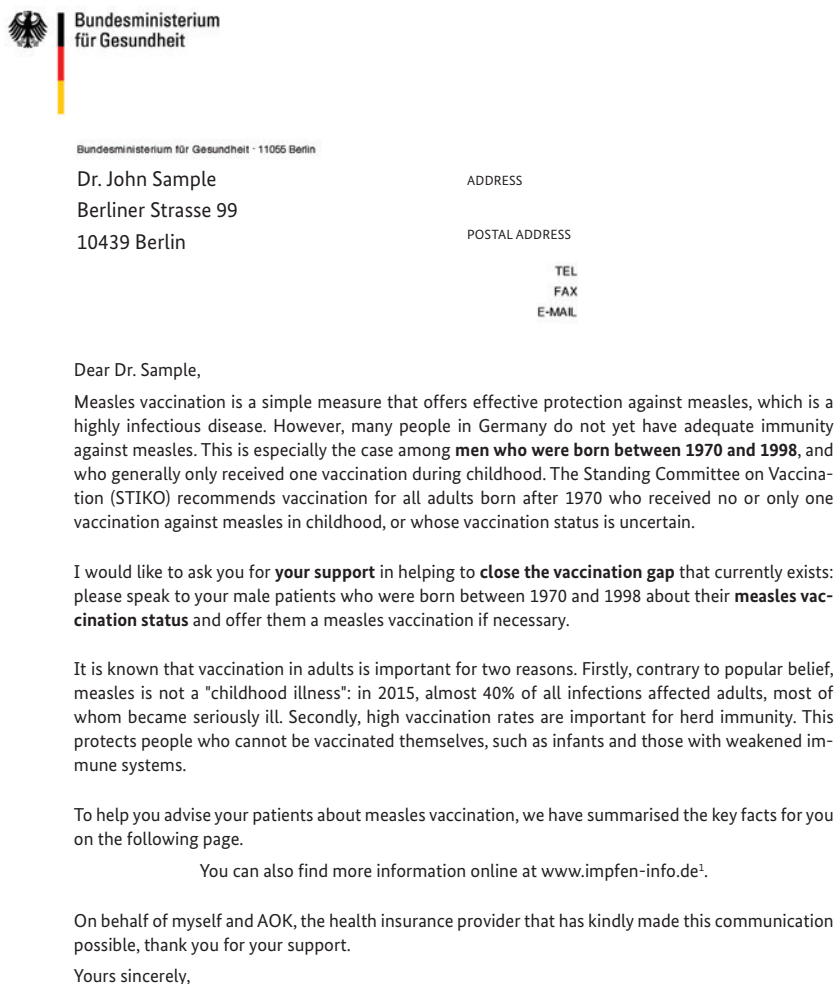
In the study, three different letters were sent to GPs. These contained a request to inform male patients³⁵ in particular born after 1970 about measles and the measles vaccination, as well as about the updated vaccination recommendations for adults. The letter was sent by the Federal Ministry of Health (BMG). All of the letters contained the information sheet for doctors on measles and the measles vaccination shown above (Figure 3). The various test groups were also differentiated as follows:

Test group 1: Request for information to be provided to patient by GP (N=1,100)

An initial group of doctors was asked to speak to patients about their measles vaccination status and the valid vaccination recommendations, inform them about the measles infection and the measles vaccination in adults and offer a vaccination if appropriate.

Figure 6 shows the letter from the BMG to the GPs in test group 1.

Figure 6: Letter from the BMG to the GPs in test group 1



¹ A service provided by the Federal Centre for Health Education (BZgA)

Test group 2: Request for information to be provided to patient by GP and in the waiting room (N=1,100)

In a second group, the doctors were also asked to use the waiting room as an additional information point and to place the BZgA information brochure there, with 150 copies of the brochure being sent out to them.

The letter to the GPs in test group 2 also contained the following paragraph (for the full letter, see *reference materials A 2.2*):

“To help you advise your patients about the measles vaccination, we have summarised the key facts for you on the following page. We are also including brochures containing further information on the MMR vaccination with this letter. We would be grateful if you could place these in your waiting room.”

Test group 3: Request for information to be provided to patient by GP and for leaflets to be handed out at reception (N=1,100)

In a third group, the doctors were asked to have the BZgA information brochure distributed to patients in the target group by a receptionist. 150 copies of the information brochure were included with the letter.

The letter to the GPs in test group 3 contained the following additional paragraph:

“To help you advise your patients about the measles vaccination, we have summarised the key facts for you on the following page. We are also including brochures containing further information on the MMR vaccination with this letter. We would be grateful if you could specifically give these to male patients born between 1970 and 1998. This could be done at reception when they arrive for an appointment, for example. This will ensure that the information is received by the patients who need it.”

Test group 4: Personal request to doctors to provide information to patients and distribute information leaflets at reception (N=703 - not randomised)

In addition to these three test groups, the doctors in a fourth group were asked in person to inform their patients about the measles vaccination. This request was made as part of a pre-arranged, routine consultation with an AOK clinical adviser. As part of the regular one-to-one consultation, the risks of measles, the importance of vaccination to achieve herd immunity, the advantages and disadvantages of vaccination and the updated RKI recommendations on measles vaccination were also discussed. The information was combined with a request that patients in the target group be given the information brochure from the BZgA at reception. A total of 703 consultations were carried out by the AOK clinical advisers. Since this group could not be chosen at random, i.e. there was no randomisation, no causal conclusions could be drawn from the observations of this group. The observations do, however, provide initial information about the effects that can be expected.

Intention-to-treat design

To understand the results, it is important to note that the design of this study is an intention-to-treat design. Only the ultimate impact on the vaccination figures is measured. This means that the actual implementation of the patient information methods in the GP surgeries was not monitored. The advantage of this study design is that the sending of letters to doctors containing information material for their patients is depicted realistically. It is not usually known what recipients do with the information after receiving it. The study design chosen here retains these typical realistic conditions in the experimental context. A review, for instance in the form of a follow-up request to GP practices, might lead to an overestimation of the expected effects because the follow-up request would make specific reference to the information provided and serve as a reminder. The disadvantage of the intention-to-treat design is that it is not possible to check the extent to which the doctors complied with the request to provide information and advice to their patients, or to what extent they were even aware of the request.

As a realistic estimation of the effects to be anticipated was the focus of this study, the advantages of this design clearly outweigh the disadvantages.

Table 1 summarises the measures in the four test groups by way of comparison.

Table 1: Overview of test groups and measures

Test group	Measures	Number of GP practices
Test group 1 Information to patients from doctor	Letter with request to GP to inform patients in a personalised consultation + information sheet for doctors	1,100
Test group 2 Information to patients from doctor and leaflet placed in waiting room	Letter with request to GP to inform patients in a personalised consultation + information sheet for doctors + BZgA information brochure to be placed in waiting room	1,100
Test group 3 Information to patients from doctor and brochure given out at reception	Letter with request to GP to inform patients in a personalised consultation + information sheet for doctors + BZgA information brochure to be handed out at reception	1,100
Test group 4 (not randomised) Information to patients from doctor and leaflet given out at reception	Consultation by clinical adviser from health insurance provider + BZgA information brochure to be handed out at reception	703

Random sample

A random sample of 3,300 GP practices was taken from operating areas in the participating AOK regions (AOKs in Bavaria, the North East, Rhineland-Palatinate/Saarland and Rhineland/Hamburg). These GP practices were randomised for each region, i.e. assigned at random to one of the test groups 1 to 3. In addition to these three randomly allocated test groups, 703 GPs in a fourth test group were personally asked to provide information to patients about the measles vaccination. This request was made as part of a pre-arranged, routine consultation with an AOK clinical adviser. This fourth group could not be assigned randomly.

The remaining 14,542 GP practices in these regions that were not assigned to any test group served as the control group.

All of the practices were asked whether patients who were insured with the participating health insurance providers and born between 1970 and 1998 received a measles vaccination during the quarter covered by the intervention. The vaccination numbers were gathered using the billing data from the practices to the participating health insurance providers. In view of the random allocation of the practices to the first three test groups, it is possible to attribute the slightly higher vaccination numbers directly to the letter and corresponding information method in each case.

Since the 703 GP practices in test group 4 could not be allocated randomly, no cause-and-effect conclusions can be drawn for this group. The fourth group was therefore analysed separately from the other groups. It provides first indications of the effect of an alternative method of recruiting GPs for targeted patient education on measles and the measles vaccination in adults.

Table 2: Number of practices in the control group and the individual test groups by region

Region	Control group	Test group 1	Test group 2	Test group 3	Test group 4
A	4,411	450	500	500	-
B	1,873	49	73	65	182
C	2,783	110	99	96	183
D	1,010	41	28	39	235
E	2,988	300	300	300	-
F	1,154	122	83	78	90
G	323	28	17	22	13
Total	14,542	1,100	1,100	1,100	703

Table 2 shows the number of cases for the test groups and the control group. The regions have been anonymised (region A to G). The GP practices in the participating AOK regions were typically led by one or two doctors and treated an average of 505 patients insured by AOK per practice in 2016. Further information on the practices can be found in the reference materials (see *reference materials A3*).

Analysis

The letters were sent out at the start of the fourth quarter of 2016. The number of measles vaccinations received by patients insured by AOK in the target group was investigated for each practice in the fourth quarter of 2016 in the participating AOK regions. The time frame of one quarter post-intervention was chosen based on the assumption that the consequence(s) of the intervention would occur in the first three months after the letter was sent.

Initially, the study looked at whether the written request to GPs to specifically inform and advise their patients about the updated vaccination recommendations had any effect on the vaccination figures. To do this, test groups 1 to 3 were aggregated and compared with the control group, i.e. with the group of GP practices that had not received any letter. The results of this comparison are set out under "Result 1: Impact of letter to GPs".

The effects in the individual test groups were also analysed. To this end, the vaccination numbers of each test group were compared with the control group. The results of this analysis are explained under "Result 2: Differences between the test groups".

To examine regional differences, the vaccination numbers were then broken down to the regional level. The results of this analysis are set out under "Result 3: Regional differences".

"Result 4: Differences between female and male patients" shows the analysis of possible gender-based differences in the effects of the measures.

The different sizes and dispatch capacities of the participating health insurance providers were taken into account in the random allocation of the test groups, so that different allocation probabilities to the test groups resulted for all AOKs. For this reason, a design weighting was performed for the calculation of the effects across all regions.³⁶ This compensates for the different assignment probabilities to the individual test groups.



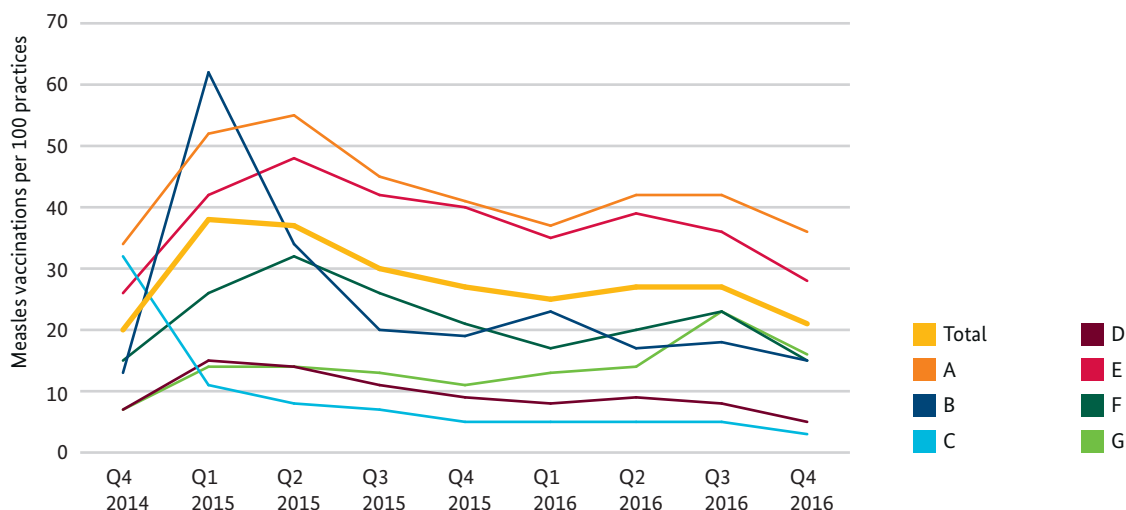
III. Results

Starting point

Vaccination data from previous years provides the point of departure. Figure 7 shows the trends in

measles vaccinations among AOK patients per 100 GP practices by region for the period from the fourth quarter of 2014 to the fourth quarter of 2016. Significant regional differences are apparent.

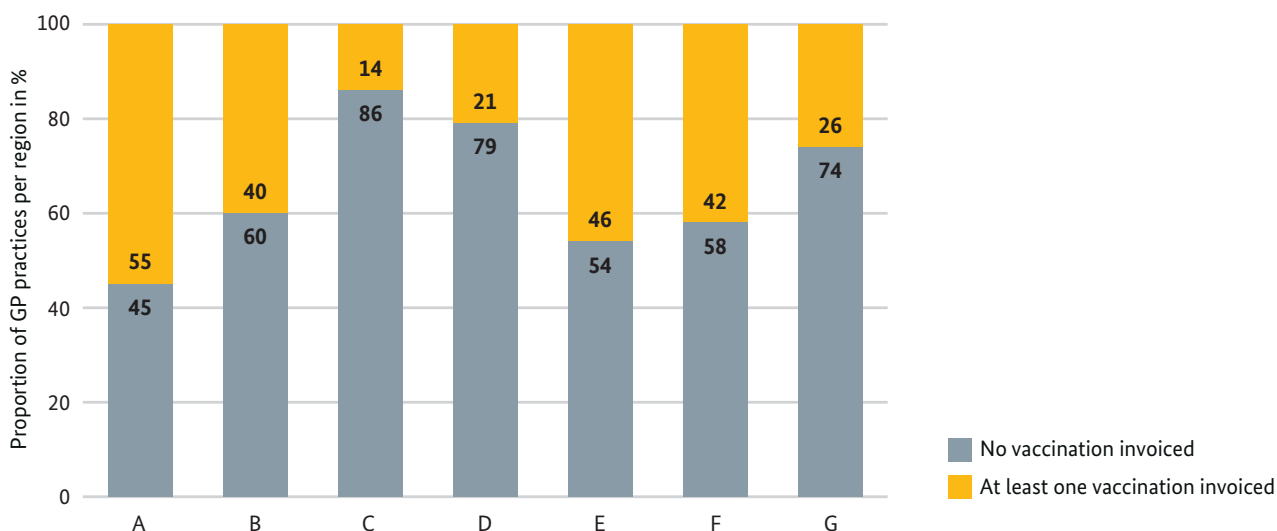
Figure 7: Measles vaccinations per 100 GP practices by region over time (without test groups 1 to 4)



An analysis of the vaccination data from the previous year (2015) shows that there are also significant regional differences in terms of the proportion of GP practices which invoiced vaccinations (see Figure 8).

The large number of practices that did not carry out a single measles vaccination in 2015 is conspicuous. This proportion varied between 45% and 86% of all practices, depending on the region.

Figure 8: Comparison of the proportion of practices per AOK region which invoiced at least one or no measles vaccinations for AOK patients in 2015

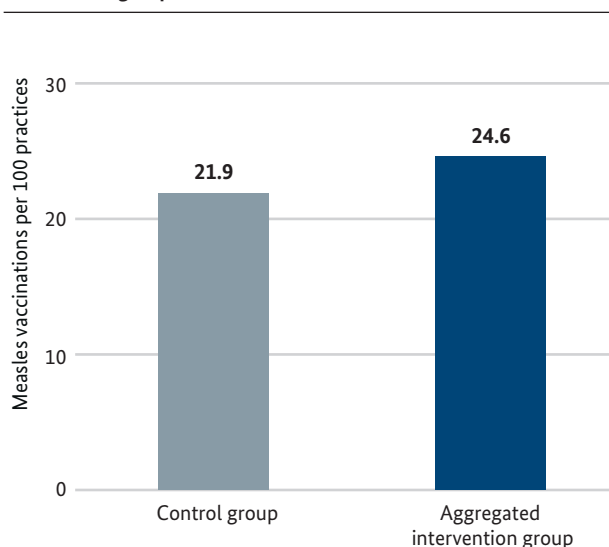


Result 1: Impact of letter to GPs

To analyse the results of this study, all of the GP practices which received a letter (test groups 1 to 3: hereafter referred to as "aggregated intervention group") were first aggregated. The aggregated intervention group was then compared with the control group, which did not receive a letter (see *Figure 9*). The comparison shows that there is no statistically significant difference in the measles vaccination rates between these two groups; the letters sent to GPs therefore had no positive effect on the vaccination numbers (regression analysis see *reference materials A 4.1*).

It should be noted that, although the original request to GPs mainly related to male patients, male and female patients are analysed together here and in the following. The reason for this is that the possibility cannot be ruled out that the practices which received a letter expanded their vaccination advice more generally as a result of the letter. Even taking gender into account, the conclusions remain unchanged.

Figure 9: Number of measles vaccinations per 100 GP practices across all regions in the fourth quarter of 2016. Control group vs aggregated intervention group



Result 2: Differences between the test groups

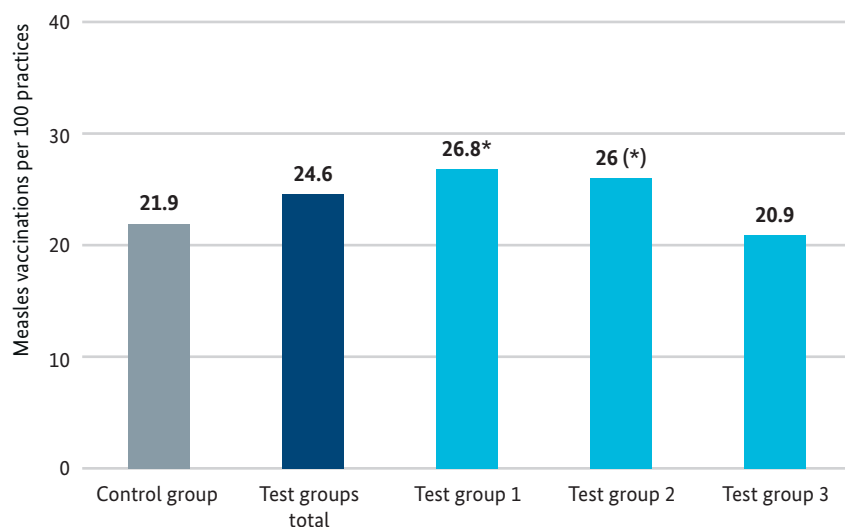
Test group 1: Individual examination of the test groups shows that the number of vaccinations in test group 1, with the request for the GP to provide information to the patient, was highest (see *Figure 10*). The number of vaccinations in this group was 4.9 vaccinations per 100 practices higher than in the control group. This effect is statistically significant for a one-tailed test (regression analysis see *reference materials A 4.2*).

This result, however, is determined by just a few practices in individual regions, which means that a robust effect cannot be assumed (cf. also *Table 3*).

Test group 2: The request for patients to be informed by the doctor and for the information brochure to be placed in the waiting room showed slightly lower vaccination numbers. In this case, the number of vaccinations was 4.1 vaccinations per 100 practices higher than in the control group. This difference is statistically marginally significant for a one-tailed test (regression analysis see *reference materials A 4.2*).

Just like with test group 1, however, this result is greatly influenced by the individual regional specifics.

Figure 10: Number of measles vaccinations per 100 GP practices across all regions in the fourth quarter of 2016. Control group vs individual test groups



*** $p < 0.001$, ** $p < 0.01$, * $p < 0.05$ (*), $p < 0.1$ ³⁷ one-tailed test

Test group 3: By contrast, the request for information to be given to patients by the doctor and for the information brochure to be given out at reception appeared not to result in any statistically significant increase in vaccination numbers compared to the control group (regression analysis see *reference materials A 4.2*).

Test group 4: In the additional test group not selected at random, in which doctors were informed by a clinical adviser, there was a comparatively low average value of 16.4 vaccinations per 100 practices following the intervention in the fourth quarter of 2016.

As it is not possible to make a direct comparison with the control group or the other test groups, the value from the previous year was used as the comparison value, i.e. the vaccination numbers from test group 4 in the fourth quarter of 2015. At 21.2 vaccinations per 100 practices, this figure was higher than in the quarter of the intervention. The difference between the two quarters, however, is not statistically significant.

A fall in vaccination activity between Q4/2015 and Q4/2016 can also be seen in the control group. Consequently, a general fall in vaccination activity can be assumed between the two periods.

Result 3: Regional differences

The point of departure for the measles vaccination numbers in the fourth quarter of 2016 was very different between the different regions (see Table 3). Whereas in the control group in region C only 3.2 vaccinations were carried out per 100 GP practices, the number in region A was significantly higher at 35.6 vaccinations per 100 GP practices. These differences were to be expected given the different vaccination coverage in the different regions and also the varying distribution of urban and rural regions.

The results in the individual test groups also demonstrate significant regional differences. Table 3 shows the number of vaccinations in the fourth quarter of 2016 per 100 practices in the various regions. Region C will be singled out to explain the results. In the control group, 3.2 vaccinations were carried out per 100 GP practices. This figure corresponds to the vaccinations that were observed on average in this region without any intervention taking place (the base rate). If the doctors were asked to lead an informative consultation with patients and to place the BZgA information brochure in the waiting room (test group 2), the number of vaccinations increased by an additional 11.9 to 15.1 vaccinations per 100 practices. This is a statistically highly significant rise in the number of measles vaccinations. This rise is not seen in the other regions, however.

Table 3: Number of measles vaccinations per 100 GP practices in the different regions in the fourth quarter of 2016

Region	Control group	Test group 1	Test group 2	Test group 3	Test group 4
A	35.6	36.4	33.8	30.4	-
B	14.5	10.2	12.3	20.0	23.6
C	3.2	3.6	15.1***	2.1	8.2
D	5.2	0	7.1	0	10.6
E	27.7	50.7	37.0	31.3	-
F	15.3	21.3	24.1	15.4	35.6
G	15.8	10.7	17.7	4.6	0
Total	21.9	26.8*	26.0(*)	20.9	-

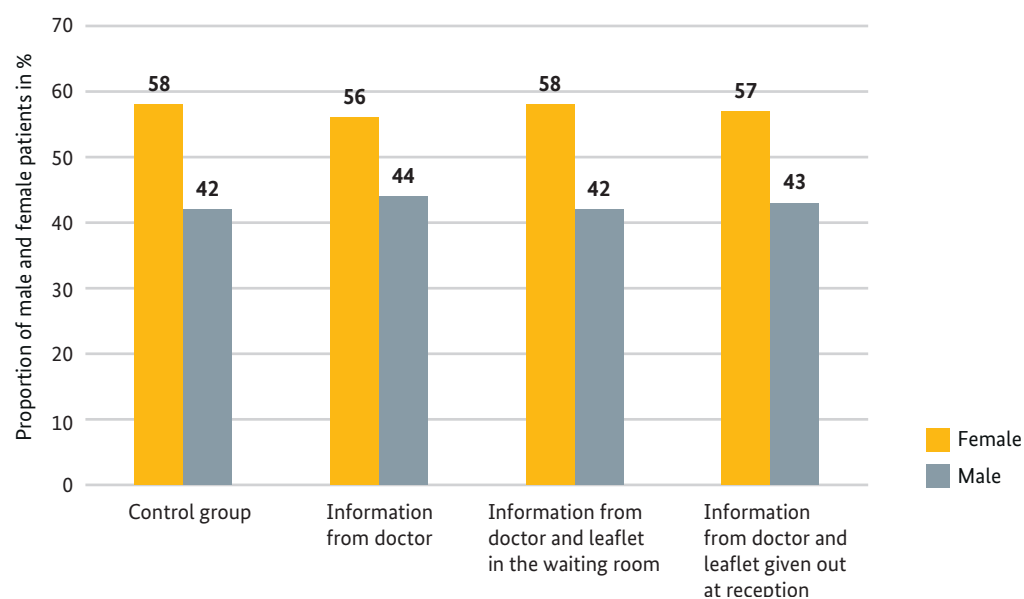
*** p < 0.001, ** p < 0.01, * p < 0.05 (*), p < 0.1³⁸ one-tailed test, relative to an average comparison with the control group in each case. For test group 4, no direct average comparisons were carried out due to the lack of randomisation.

Result 4: Differences between female and male patients

During the period of observation, from the start to the end of the fourth quarter of 2016, more women than men were vaccinated. This is true both for the control

group and the various test groups. Figure 11 shows the proportion of female and male patients who were vaccinated against measles in the fourth quarter of 2016. There is no gender difference in terms of the effect of the measures.

Figure 11: Proportion of female and male patients who were vaccinated against measles in the fourth quarter of 2016. Control group vs individual test groups



Discussion and summary of results

The idea of involving GPs, as disseminators and significant persons trusted by patients, in the targeted education of patients about vaccinations is frequently discussed in professional circles as an effective means of closing the measles vaccination gap in adults.

The results of this study show that a written request from the Federal Ministry of Health to GPs to specifically inform their patients about the updated vaccination recommendations did not have any demonstrable effect on vaccination rates. Although there were major regional differences, the overall view shows that this measure was unable to increase the number of measles vaccinations given. The request for support in educating patients as part of personalised consultations with clinical advisers from health insurance providers yielded a similar result. Here too, there was no evidence of any reliable increase in vaccination numbers.

One possible explanation for this is that only a few GPs heeded the request to provide targeted patient information. A possible reason for this is that GPs assume that patients will already have been sufficiently informed about the measles vaccination recommendations and about measles in adults. Other possible barriers to action for GPs may include the timeframes available for patient consultations, the remuneration structure and a possible negative attitude on the part of patients towards the topic of vaccination. GPs also receive frequent requests to display information in their waiting room. Other measures may therefore be more effective in recruiting GPs to provide targeted information to their patients as they are more likely to be seriously considered. However, based on the initial indications from this study, the method involving the clinical adviser from the health insurance provider is also only of limited suitability.

One alternative explanation for the results of this study is that the GPs may in fact have complied with the request to inform their patients, but patients nevertheless decided against vaccination after being informed about the current vaccination recommendations. This alternative explanation cannot be ruled out. However, a comparison with the impact of an information letter sent directly to the patient, which was investigated by *wirksam regieren* in a parallel study, would seem to refute this explanation. This is because, in comparison with the present study, direct information to patients through an information letter

from health insurance providers had a reliable impact on closing the measles vaccination gap among adults. That study showed that the vaccination numbers were increased from 3 to 8 vaccinations per 1,000 patients if the patients were given information regarding the measles vaccination directly by their health insurance provider. The results of that study can be found in the report titled "Information on the measles vaccination - Analysis of information provided by post regarding measles vaccination for adults" by the *wirksam regieren* division.³⁹

The results of both studies illustrate that the various measures differ considerably in their effectiveness. A comparison of the two studies has been published on the website www.bundesregierung.de/wirksam-regieren. They demonstrate the contribution that impact analyses can make to project planning. Early impact analyses of alternative actions can allow effective measures to be identified and evidence-based actions to be taken.

End notes

- ¹ Robert Koch Institute. Epidemiological Bulletin (2015). 23 November 2015 No. 47/48.
- ² WHO. Measles. Fact sheet. [accessed 4 May 2018] Available at: www.who.int/en/news-room/fact-sheets/detail/measles
- ³ Measles is regarded as having been eliminated in a country when there is no evidence of endemic person-to-person transmission over a period of 12 months.
- ⁴ Robert Koch Institute (2018). Aktuelle epidemiologische Situation der Masern und Röteln in Deutschland. https://www.rki.de/DE/Content/Infekt/Impfen/Praevention/elimination_04_01.html
- ⁵ The following indicators apply for the implementation of successful strategies to eliminate measles in the WHO Europe region: (1) Reduction of measles incidence to less than one case of measles in 1 million inhabitants and maintenance thereof. For Germany, this corresponds to fewer than 80 cases of measles per year. (2) The attainment of a long-term vaccination rate of at least 95% for 2 MMR vaccinations and (3) the use of an adequate and high-quality surveillance system for verifying cases of measles.
- ⁶ Federal Ministry of Health (2015). 2015 - 2020 National Action Plan to Eliminate Measles and Rubella in Germany. Backgrounds, goals and strategy. Available at: www.bundesgesundheitsministerium.de/mrp15-20.
- ⁷ Robert Koch Institute (2017). Recommendations of the Standing Committee on Vaccination (STIKO) at the Robert Koch Institute - 2017/2018. Epidemiological Bulletin, 24 August 2017 / No. 34.
- ⁸ See end note 6
- ⁹ See end note 7
- ¹⁰ Ommen, O., Reckendrees, B., Seefeld, L., & Stander, S. (2014). Einstellungen, Wissen und Verhalten der Allgemeinbevölkerung zum Infektionsschutz, Federal Centre for Health Education BZgA, Cologne.
- ¹¹ See end note 6
- ¹² The other study focuses on the impact of information about the measles vaccination sent directly to customers by their health insurance provider. This study was carried out in cooperation with the Techniker Krankenkasse and can be accessed at <http://www.bundesregierung.de/Content/DE/StatischeSeiten/Breg/wirksam-regieren/Anlagen/Download-Masernimpfung-I.html>.
- ¹³ Wahle, K. (2009). Aufgabe und Verantwortung des Hausarztes bei der Impfkontrolle. *DMW-Deutsche Medizinische Wochenschrift*, 134 (S 02), pp. 65 - 70; Horstkötter N., Müller U., Ommen O. Platte A., Reckendrees B., Stander V., Lang P. Thaiss H. (2017). Einstellungen, Wissen und Verhalten von Erwachsenen und Eltern gegenüber Impfungen -Ergebnisse der Repräsentativbefragung 2016 zum Infektionsschutz. BZgA research report. Cologne: Federal Centre for Health Education (Bundeszentrale für gesundheitliche Aufklärung).
- ¹⁴ The results of this study can be found in the report entitled "Information on the measles vaccination - Analysis of information provided by post regarding measles vaccination for adults". Available from: <http://www.bundesregierung.de/Content/DE/StatischeSeiten/Breg/wirksam-regieren/Anlagen/Download-Masernimpfung-I.html>
- ¹⁵ See end note 4
- ¹⁶ See end note 7
- ¹⁷ See end note 7
- ¹⁸ See end note 4
- ¹⁹ The measles vaccination was introduced in 1970. It is assumed that people born before 1970 will have survived a bout of measles and will therefore largely be protected. In addition to age differences in relation to immunity, there are also significant regional differences. In the western federal states there is a significantly higher incidence of measles compared to the eastern federal states. This is partly due to the fact that vaccinations were mandatory in the GDR, whereas in the former FRG they were not.
- ²⁰ Poethko-Müller, C., & Schmitz, R. (2013). Impfstatus von Erwachsenen in Deutschland. Ergebnisse der Studie zur Gesundheit Erwachsener in Deutschland (DEGS1) *Bundesgesundheitsblatt* 2013, 56: 845-857, DOI 10.1007/s00103-013-1693-6.
- ²¹ Poethko-Müller, C. & Schmitz, R. (2013). Impfstatus von Erwachsenen in Deutschland. *Bundesgesundheitsblatt* 56, 845 – 857
- ²² Ommen, O., Reckendrees, B., Seefeld, L., & Stander, S. (2014). Einstellungen, Wissen und Verhalten der Allgemeinbevölkerung zum Infektionsschutz, Federal Centre for Health Education (BZgA), Cologne.
- ²³ See end note 6
- ²⁴ Betsch, C., Böhm, R., & Chapmann, G. (2015). Using Behavioral Insights to Increase Vaccination Policy Effectiveness. *Policy Insights from the Behavioral and Brain Sciences*, 2 (1), 61–73.
- ²⁵ McDowell M, Rebitschek F, Gigerenzer G, Wegwarth O. (2016). A Simple Tool for Communicating the Benefits and Harms of Health Interventions. *MDM Policy & Practice*.
- ²⁶ Artinger, S., Balthes, S., Jarchow, C., Petersen, M., Schneider, A. M. (2018). Information on the measles vaccination – Analysis of information provided by post regarding measles vaccination for adults. Available from: <http://www.bundesregierung.de/Content/DE/StatischeSeiten/Breg/wirksam-regieren/Anlagen/Download-Masernimpfung-I.html>
- ²⁷ Wahle, K. (2009). Aufgabe und Verantwortung des Hausarztes bei der Impfkontrolle. *DMW-Deutsche Medizinische Wochenschrift*, 134 (S 02), pp. 65 - 70.
- ²⁸ Horstkötter N., Müller U., Ommen O. Platte A., Reckendrees B., Stander V., Lang P. Thaiss H. (2017). Einstellungen, Wissen und Verhalten von Erwachsenen und Eltern gegenüber Impfungen -Ergebnisse der Repräsentativbefragung 2016 zum Infektionsschutz. BZgA research report. Cologne: Federal Centre for Health Education (Bundeszentrale für gesundheitliche Aufklärung).
- ²⁹ See end note 27
- ³⁰ McDowell, M., Jacobs, P. (2017). Meta-analysis of the effect of natural frequencies on Bayesian reasoning. *Psychological Bulletin*, 143, 1273-1312; Hoffrage, U., Gigerenzer, G. (1998). Using natural frequencies to improve diagnostic inferences. *Academic Medicine*, 73, 538-540; Akl, E., Oxman, A., Herrin, J., Vist, G., Terrenati, I., Sperati, F. (2011). Using alternative statistical formats for presenting risk and risk reduction. *Cochrane Database Syst Rev* 2011. (4): CD006776.
- ³¹ Hoffrage, U., Lindsay, S., Hertwig, R. & Gigerenzer, G. (2000). Communicating statistical information. *Science*, 290, 2261 – 2262; Edwards, A1, Elwyn, G., Covey, J., Matthews E. & Pill, R. (2001). Presenting risk information - A review of the effects of "framing" and other manipulations on patient outcomes. *J Health Communication*, Volume 6, 61-82; Jungermann, H. & Benighaus, L. (2016). Kommunikation gesundheitlicher Risiken. In: Benighaus, L., Renn, O. & Benighaus, C. (Ed.). *Gesundheitsrisiken im gesellschaftlichen Diskurs*, 35-65, Bremen: EHV academicpress.
- ³² Notice of the recommendations regarding the design of packaging leaflets as per Section 11 of the Medicinal Products Act (AMG) for medicines used in humans (as per Section 77 Para 1 AMG) and the requirements of Section 22 Para 7 Sentence 2 of the AMG (reviewing the comprehensibility of packaging leaflets). Federal Institute for Drugs and Medical Devices.
- ³³ http://ec.europa.eu/health/documents/eudralex/vol-2/index_en.htm

³⁴ Coulter, A., & Ellins, J. (2007). Effectiveness of strategies for informing, educating, and involving patients. *BMJ: British Medical Journal*, 335(7609), 24. Redman, S., & Paul, C. L. (1997). A review of the effectiveness of print material in changing health-related knowledge, attitudes and behaviour. *Health Promotion Journal of Australia: Official Journal of Australian Association of Health Promotion Professionals*, 7(2), 91.

The request was mainly related to male patients, as the largest vaccination gap exists in this group, see Poethko-Müller, C. & Schmitz, R. (2013). *Impfstatus von Erwachsenen in Deutschland*. *Bundesgesundheitsblatt* 56, 845 – 857.

³⁶ For design weighting, see Gabler, S., Kolb, J.-P., Sand, M. & Zins, S. (2015). *Gewichtung*. Mannheim, GESIS – Leibniz Institute of Social Sciences (GESIS Survey Guidelines). DOI: 10.15465/gesis-sg_007

³⁷ *** = very highly significant ($p < 0.001$), ** = highly significant ($p < 0.01$), * = significant ($p < 0.05$), (*) = tendentially significant ($p < 0.1$). "Significant" means that the probability of error is 5% or less.

³⁸ See end note 37

³⁹ See end note 26

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With citizens for citizens - the *wirksam regieren* government strategy

"We want to increase the *delivery* and *effectiveness* of political projects by developing these projects more from the perspective of and with *participation* from citizens."

Source: coalition agreement between CDU, CSU and SPD in December 2013

The Federal Government has followed through on his goal from the coalition agreement of December 2013. The *wirksam regieren* Division in the Federal Chancellery has been supporting ministries and other government agencies since 2015 in getting citizens involved in the design and continuous improvement of specific projects.

Whether law or administrative rule administrative processes or a simple form - the state has a wide variety of options for organising society and pursuing political goals. For each of these cases, these questions need to be answered: what is the optimal design and how should the implementation look like for achieving the political goal in question?

For selected political projects, *wirksam regieren* tests alternative options for design and implementation. This is done very practically, under realistic conditions and in dialogue with citizens.

Understanding.

The first step of each project is to understand the situation and the viewpoint of all stakeholders.

To this end, and depending on the details of the project, input is collected from citizens, consumers, or users on questions such as: do the affected parties benefit in the intended manner from a proposed policy? how do citizens experience public services and where do they see potential for improvement? Are forms, applications and legal language easy to understand and clear? Is the information provided to consumers helpful?

Wirksam regieren works interdisciplinarily and builds on the latest findings of the empirical social sciences. For example, behavioural and decision sciences provide insights into how people deal with information or perceive processes.

Designing.

In a second step, design alternatives for a proposed policy are developed from these results.

Wherever appropriate, citizens are involved in this process of developing design alternatives. Citizens' experiences and viewpoints are thus taken into account.

Testing.

The various design options are empirically tested with a view to their actual effect, user-friendliness or clarity. Issues can be identified early on to optimize delivery and implementation.

Evaluating.

Ministries or authorities define the research question and the project scope. *Wirksam regieren* formulates and implements the research design, collects data and evaluates it.

The results become part of the political process and decision-making in the ministries and government agencies.

The benefits of this approach: the effectiveness of political projects can be optimised from the citizens' point of view: laws and programmes become more targeted. Information is made clearer. Forms, processes and legal language become simpler. Unnecessary bureaucracy is avoided and taxpayers' money is saved.

By incorporating scientific expertise along with citizens' ideas and viewpoints better solutions for an effective policy making process can be achieved.

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"Information provided to patients about measles vaccinations in general practices (GP)" report & reference materials:
<https://www.bundesregierung.de/breg-en/issues/wirksam-regieren-with-citizens-for-citizens/topics/measles-vaccination-protection-for-everyone-323382>

