Progress towards measles and rubella elimination in Tuscany, Italy: the role of population seraepidemiological profile

Angela Bechini1, Sara Boccalini1, Emilia Tiscione1, Giovanna Pesavento1, Francesco Mannelli2, Marta Peruzzi2, Stefano Rapi3, Stefano Mercurio3, Paolo Bonanni1

1 Department of Public Health, University of Florence, Florence, Italy
2 Emergency Department, Paediatric Hospital A. Meyer, Florence, Italy
3 Azienda Ospedaliera-Universitaria Careggi, University of Florence, Florence, Italy

Correspondence: Paolo Bonanni, Department of Public Health, University of Florence, Viale Morgagni, 48 50134 Florence, Italy, tel: +39 055 4598511, fax: +39 055 4598935, e-mail: paolo.bonanni@unifi.it

Background: As a part of the National Plan for Measles and Congenital Rubella Elimination, a catch-up campaign targeting children aged 7–14 years with Measles–Mumps–Rubella (MMR) vaccine was conducted during 2004–05 in Tuscany, Central Italy. Methods: To assess the profile of measles and rubella susceptibility, immunoglobulin G antibodies against measles (945 subjects) and rubella (1110 subjects) were detected using two commercial enzyme-linked immunosorbent assay tests in sera from a population aged 1–49 years. Results: Overall immunity towards measles increased in the last years, but the WHO-Euro recommended threshold of susceptibility for elimination was attained only in 2- to 4-year-olds. All fertile women up to 29 years had rates of susceptibility clearly higher than those required by WHO-Euro (5%) to eliminate congenital rubella. Despite the reduction of susceptibility among subjects targeted by the catch-up campaign, continuous efforts to increase immunization coverage are needed to eliminate measles and rubella circulation. Our results are predictive of a high chance of measles and rubella outbreaks because of the accumulation of susceptible individuals. Conclusion: Additional catch-up vaccination strategies targeting the adult population (particularly fertile women) are strongly needed to eliminate the risk of measles and congenital rubella syndrome for future generations.

Introduction

Infections due to measles and rubella viruses are an important concern of public health in Italy, where the implementation of the National Plan of Measles and Congenital Rubella Elimination (NPMCRE) was carried out since 2003.1 Actions taken for the implementation of NPMCRE were of high quality both in terms of surveillance of suspected cases, prevention of new infections and monitoring of susceptibility in the regional population. Susceptibility thresholds for the elimination of measles in the European population were set by World Health Organization (WHO) at 15% in children between 0 and 4 years, 10% between 5 and 9 years and 5% in subjects >10 years; the susceptibility threshold for the elimination of congenital rubella is 5% in fertile-age women (15–49 years).

Historical changes in measles and rubella surveillance and recommendation for immunization in Italy are presented in figure 1.2 During the implementation of the NPMCRE, in order to monitor progress towards measles elimination and congenital rubella prevention, measles and rubella surveillance has been strengthened, including laboratory investigation of all suspected measles and rubella cases, with a particular attention to rubella cases in pregnant women. Starting from 1 January 2005, a special surveillance of rubella infections in pregnancy and congenital rubella syndrome (CRS) was re-introduced at national level.3

In Tuscany (Central Italy) historical changes in vaccination strategies replicated the Italian national steps. During the 1970s and the 1980s the two recommended vaccines were often administered by private paediatricians and records are not available. According to the ICONA surveys (national vaccination coverage surveys based on the cluster sampling method as recommended by

References

WHO) performed in 1993, 1998 and 2003, the coverage with the first dose of MMR vaccination in 24-month-old children ranged from 9 to 53% in different Italian regions in 1993, raised to a national average of 56% in 1998 (range 26–88%) and to 77% (range 55–90%) in 2003. In Tuscany, in the same years, these levels were higher than the national average with values of 44.4, 64.8 and 87%, respectively. In addition, MMR vaccination coverages in Tuscany rose from 87.6% in 2004 to 91.2% in 2006.4–7

According to WHO recommendations, all countries with low immunization coverage (<90%) for the first MMR dose, with frequent measles outbreak and many susceptible subjects in age groups not targeted by immunization programmes, like Italy, should improve immunization coverage for the first dose in 2-year-old children and should catch-up all susceptible subjects in older age groups, through supplementary immunization campaigns.

The main expected outcomes of the Italian NPMCRE were the achievement and maintenance by the end of 2010 of high immunization coverage with the first dose of MMR vaccine (95%) in 24-month-old children, and for the second dose (90%) in school-aged children. Another important objective was to monitor the susceptibility to measles and rubella in the general population, with the intention to determine risk groups and address possible additional immunization strategies.

In order to evaluate the impact of the immunization campaigns performed in Tuscany during 2004 and 2005 in school-aged children (7–14 years), and to establish the susceptibility of the Tuscan population, a seroepidemiological survey was planned for both measles and rubella infections. A previous survey, carried out in Tuscany in 2003 (before the implementation of the NPMCRE), on a total of 552 serum samples (279 males, 273 females, age range 1–49 years) of the resident Tuscan population at 1 January 2004, was collected from June 2005 to July 2006.

Serum samples belonged to a population aged 1–49 years and were stratified into the following age groups: 1, 2–4, 5–9, 10–14, 15–19, 20–24, 25–29, 30–39 and 40–49 years. Each stratum maintained the same sample size (0.5%) of the respective age group of the general Tuscan population. In this way, no standardisation of results was required, being the sample size of each stratum proportional to the respective resident population. Samples were collected in an anonymous way: only age, sex and day of collection were recorded. Sera belonging to individuals of paediatric age affected by immunosuppressive conditions were excluded. In the adult age groups, only sera withdrawn from outpatients whose blood was taken for routine investigations were included.

All 1110 sera were tested for rubella antibodies, while 945 sera (461 males, 484 females) were tested for measles antibodies. Serum samples were stored at −20°C until tests were performed.

Results of the 2006 survey on measles antibodies, were compared with those of a previous survey conducted in Tuscany in 2003 (before the implementation of the NPMCRE), on a total of 552 serum samples (279 males, 273 females, age range 1–49 years, corresponding to 0.3% of the resident Tuscan population at 1 January 2004) collected from the same two hospitals, using the same sample selection criteria and the same detection kits. Results were also compared with available national data.

For rubella antibodies, the 2006 Tuscan serosurvey was compared only with the available national data.

**Methods**

**Collection of serum samples**

Serum samples from the general population of Tuscany (total: 3.5 million inhabitants) were collected from two reference regional hospitals of Florence: University Hospital of Careggi and Meyer Paediatric Hospital. The two hospitals are the most important in Tuscany, and individuals from the entire Regional territory apply to those structures for diagnosis and care. For this reason the collected samples are representative not only of the city of Florence, but of the Region in general. Sera from subjects of paediatric age, representing one-third of the sample, were collected from the emergency department of the paediatric hospital Meyer, while sera from other age groups were collected at the outpatient laboratory of the regional hospital Careggi in Florence. A sample of 1110 (511 males, 599 females) anonymous residual sera, corresponding to 0.5% of the resident Tuscan population at 1 January 2006, was collected from June 2005 to July 2006.

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**Antibody testing**

The commercial enzyme linked immunosorbent assays (ELISA) Enzygnost Anti-Masern-Virus/IgG and Enzygnost Anti-Rubella-Virus/IgG (Dade Behring, Germany) were used for detection of measles and rubella IgG antibodies.

The following criteria were applied for the qualitative evaluation of antibodies: negative (absorbance difference measured in presence and in absence of the measles or rubella antigen or \(\Delta A<0.100\), cut-off value, corresponding to about 4 IU/ml), positive (\(\Delta A>0.200\)), equivocal (0.100 ≤ \(\Delta A\) ≤ 0.200). All equivocal sera were tested twice in order to establish the positive or negative value. All \(\Delta A\) were multiplied.

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by the correction factor resulting by the ratio of nominative value and mean ΔA value for reference positive and negative controls (P/N).

**Statistical analysis**

Frequencies and percentages of positive and negative samples were calculated and compared to the WHO-Euro epidemic thresholds recommended for each age group for the elimination of measles and congenital rubella. Differences among frequencies of seropositive subjects were calculated by the Chi-square test (by paired age groups and for linear trend).

Statistical analysis was performed using the Stata 9 software (StataCorp LP, College Station, TX, USA).

Incidence data for measles and rubella were calculated by dividing the number of notified cases in Tuscany by the resident Tuscan population for each age group.

**Results**

**Rubella**

Data on seroprevalence of rubella antibodies by gender are reported in table 1.

The results of the seroepidemiological survey for rubella antibodies detection showed a total seropositivity rate of 90.6%; considering only the female population, this percentage increased to 92.8%.

In all age groups, the seroprevalence of rubella antibodies was >80%, except for the sera of 1-year-old subjects.

The chi-square test for linear trend showed a statistically significant increase in the seropositivity values with increasing age (P < 0.001).

Although, on the whole sample (1110 sera), a higher proportion of seropositives was found in females compared to males (P = 0.006), when the sample is considered by gender and age group, differences between genders were statistically significant only in two age groups (2–4 years, P = 0.02; 10–14 years, P = 0.001).

The results of serological tests shown as percentages of seronegative women at childbearing age (15–49 years) are shown in figure 2.

The WHO-Euro threshold for the elimination of congenital rubella (5%) was exceeded in all women aged 15–29 years. On the other hand, in the age group 30–39 years, the desired threshold was almost achieved (6.4%); only in the last age group (40–49 years), the percentage of susceptible women resulted under the WHO-Euro threshold (4.5%).

**Measles**

The results of the seroepidemiological surveys for measles antibodies detection, performed in 2005–06 and in 2003 in Tuscany, and the Italian seroprevalence data, are shown in table 2.15

For the 2005–06 survey in Tuscany, a total seropositivity rate of 84.3% was detected.

No statistical significant differences in seroprevalence were observed between genders (85.1% positive female sera and 83.5% positive male sera). Sera from 1-year-olds showed a seroprevalence of 63.2%, in the age groups from 2 to 9 years, seroprevalence was over 80%; from 10 to 24 years was between 60 and 74%; in the age group 25–29 years,

**Table 1 Rubella seroprevalence in Tuscany, by age group and gender in 2005–06 [n/N=seropositive samples/total]**

<table>
<thead>
<tr>
<th>Age groups (years)</th>
<th>Males seropositive</th>
<th>Females seropositive</th>
<th>Total seropositive</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n/N (%)</td>
<td>% (95% CI)</td>
<td>n/N (%)</td>
</tr>
<tr>
<td>1</td>
<td>5/8 (62.5)</td>
<td>(24.4–91.4)</td>
<td>8/11 (72.7)</td>
</tr>
<tr>
<td>2–4</td>
<td>32/39 (82.1)</td>
<td>(66.4–92.4)</td>
<td>26/26 (100)</td>
</tr>
<tr>
<td>5–9</td>
<td>49/56 (87.5)</td>
<td>(75.9–94.8)</td>
<td>42/47 (89.4)</td>
</tr>
<tr>
<td>10–14</td>
<td>41/53 (77.4)</td>
<td>(63.7–87.7)</td>
<td>39/39 (100)</td>
</tr>
<tr>
<td>15–19</td>
<td>23/30 (76.7)</td>
<td>(57.7–90.0)</td>
<td>35/39 (89.7)</td>
</tr>
<tr>
<td>20–24</td>
<td>21/28 (75.0)</td>
<td>(55.1–89.3)</td>
<td>40/46 (87.0)</td>
</tr>
<tr>
<td>25–29</td>
<td>40/41 (97.6)</td>
<td>(87.1–99.9)</td>
<td>59/66 (89.4)</td>
</tr>
<tr>
<td>30–39</td>
<td>107/116 (92.2)</td>
<td>(85.7–96.3)</td>
<td>160/171 (93.6)</td>
</tr>
<tr>
<td>40–49</td>
<td>132/140 (94.3)</td>
<td>(89.0–97.5)</td>
<td>147/154 (95.5)</td>
</tr>
<tr>
<td>Total</td>
<td>450/511 (88.1)</td>
<td>(84.9–90.7)</td>
<td>556/599 (92.8)</td>
</tr>
</tbody>
</table>

Cl, confidence interval

**Figure 2** Incidence of rubella cases in Tuscany in 2006 from 15 to 49 years (incidence/100 000 inhabitants = solid line), percentages of seronegative sera (sbars and relevant numbers on their top) in the female serum samples collected in 2005–06 (476 sera), and WHO-Euro threshold of susceptibility (= dashed line) for the elimination of congenital rubella in childbearing age women (15–49 years)
seroprevalence increased to 84.4%, while in the older age groups the seroprevalence was ~95%.

Analysing data on seroprevalence of antibodies to measles by age group, statistically significant differences were found comparing 1-year-old infants (63%) with the 2- to 4-year age group (88%) (\( P = 0.014 \)); the 5–9 (82%) with the 10–14 years (63%) age groups (\( P = 0.002 \)); the 15–19 (62.6%) with the 20–24-year (73.9%) age groups (\( P = 0.002 \)); and the 20–29 (84.4%) with 30–39 years (76.2%) age groups (\( P < 0.001 \)). (Data not shown in table 2.)

The chi-square test for linear trend shows a statistically significant increase in the seropositivity values with increasing age (\( P < 0.001 \)) for both seroepidemiological surveys (2005–06 and 2003).

As to the 2003 seroepidemiological survey, a total seropositivity rate of 80.4% was detected. No statistical significant differences in seroprevalence were observed between genders in the 2003 seroepidemiological survey (77.4% positive male sera and 83.5% positive female sera). The age groups with higher incidence values of notified measles cases were represented by the first three age groups (from 1 to 9 years), in which our 2003 survey confirmed a susceptibility over 20%.

In figure 3, a comparison between seronegative samples found in both Tuscan serosurveys of 2003 and 2005–06 is shown. No statistical significant differences were found between the two surveys comparing the age groups, except for the age group 2–4 years (\( P = 0.043 \)).

**Equivocal sera**

Analysing the results of the 2005–06 seroepidemiological measles survey, a percentage of 2.2% (21 sera) resulted as equivocal sera. The number of
equivocal sera is predominant in the age groups from 10 to 24 years. A total of 32 sera corresponding to a higher percentage of equivocal sera (5.8%) were found in the 2003 seroepidemiological measles survey. In that survey, the number of equivocal sera was predominant in the age groups from 5 to 24 years.

Discussion

A seroepidemiological survey for both measles and rubella infections was performed in order to evaluate the impact of the immunization campaigns carried out in Tuscany during 2004 and 2005 in school-aged children and to establish the susceptibility of Tuscan population to both infections with particular attention to susceptibility of childbearing age women to rubella.

Rubella

The results of the seroepidemiological survey for rubella antibodies detection showed a total seropositivity of 90.6%; considering only the female sample, this percentage increased to 92.8%, probably due to the Italian selective vaccination strategy of pre-adolescent girls in place during the 1970s and the 1980s (figure 1).

The chi-square test for linear trend shows a statistically significant increase in the seropositivity values while getting older (P < 0.001), as expected for the combined effect of natural immunization and vaccination (table 1). Nevertheless, the association between various immunization strategies and immunity acquired by natural infection led to the large prevalence (>5%) of susceptible female population.

At all ages, the seroprevalence of rubella antibodies is >80%, except for the sera of 1-year-olds, due to the progressive loss of maternal antibodies and the later scheduled administration of the first dose of MMR, recommended at age 12–15 months.

Our survey shows that percentages of susceptible fertile women are still too high to reach CRS elimination. As a matter of fact, the WHO-Euro threshold of susceptibility (5%) was exceeded in all females up to 29 years (range: 10–13% seronegative).

Additional vaccination strategies for the catch-up of all susceptibles should therefore be targeted to this group of childbearing age women.

A further confirmation of these susceptibility data comes from official notifications, which show that the highest incidence of rubella cases in the period 2005–08 in Tuscany was registered in the 15–24 years age range.11

The results of the 2006 seroepidemiological survey for measles antibodies detection showed a total seropositivity of 84.3%, and no statistically significant differences were observed between genders (table 2). This is an expected result since no selective vaccination strategy was adopted in the past for males or females. A statistically significant increase in the seropositivity values was observed in the seroepidemiological survey with increasing age, due to the combined effect of natural infection and active immunization (P < 0.001). In particular, the first comparison between 1-year-old children and 2- to 4-year-old subjects is statistically significant, due to the progressive loss of maternal antibodies and the scheduled administration of the first dose of MMR, recommended at age 12–15 months of life. The age group 5–9 years (born around 1996–2000) showed a seroprevalence profile for measles antibodies (82.2%) which is significantly higher than the seroprevalence observed in the 10–14-year-old age group (62.6%). This result is related to a higher vaccination coverage from 1998 to 2002 (from 64.8 to 85%) at 24 months of age, in comparison to the vaccination coverage (~44%) registered for the present cohort of 10- to 14-year old (born in 1991–95) at the time they were 2 years old and to the lower measles virus circulation in the same years.

In the age group 15–19 years, the seroprevalence observed was 60.3%, similar to the 10- to 14-year-old age group. From 20-year-old subjects onwards, the seroprevalence was >85%, probably due to higher measles virus circulation in the years before 1985 (protection acquired much more by natural infection than by vaccination coverage). As a matter of fact, during the 1980s, no vaccination strategies were actively implemented in Italy or in Tuscany.

From this 2005–06 serosurvey (figure 3), it turns out that only in the 2–4 years age group the objective (threshold of susceptibility) indicated by WHO for the EU Region was reached (<15% susceptible subjects). The increase in seroprevalence observed between the 2003 and the 2006 serosurvey in the same age group (2–4 years) is statistically significant. This result should be due to the increasing uptake of MMR vaccine in the pediatric population of Tuscany.

In the 2006 serosurvey, seronegative samples in the 5–9 years age group were near the WHO-Euro threshold (15.8% instead of 10%). A decrease in susceptibility was observed between 2003 and 2006, in the age groups 5–9 and 10–14 years, although this difference is not statistically significant. In Tuscany, the catch-up campaign in the primary schools during 2004, led to an increase in the vaccination coverage (children born in 1994–97) from 79 to 88% for the first dose, and a higher increase for the second dose from 38 to 66%. However, during this catch-up campaign, a total of ~10% of vaccination refusals was
registered. The target population of the catch-up campaign in Tuscany involved over 160,000 children attending primary and lower secondary schools (born in 1991–97, 7–14 years old), i.e. about 85% of the resident Tuscan population in the same age groups. At the end of 2005, the vaccination coverage in such population reached 88.2% for the first dose, and 64.7% for the second dose. The results of our 2006 serosurvey show a lower seroprevalence of measles antibodies (~63%) in 10- to 14-year-olds, probably due to the high percentage of refusals during the catch-up campaign and the fact that not all the resident population was included in the catch-up activities (~74% of children between 7 and 14 years).

In 2006, a large part of the general population between 10 and 29 years was susceptible, with percentages of seronegatives always >15%. This fits well with the age groups showing the highest incidence of measles observed in Tuscany in 2006. Only in the age groups >30 years, seronegative subjects were <5% (WHO-EURO threshold). This finding demonstrates the epidemiological shift in the susceptibility of the population towards older age groups in 2006 with respect to the 2003 survey.

Taking into consideration the high susceptibility to measles in the population from 15 to 30 years, an ‘ad hoc’ strategy of vaccination in these age groups should be enforced in order to increase the vaccination coverage and to catch-up young adults, who are today the most susceptible to measles in our epidemiological context.

While for the female population from 15 to 30 years programmed opportunities for vaccination promotion (like HPV vaccination during adolescence or pap-test screening starting from the age of 25 years), already exist, for the male population other occasions for the promotion of MMR vaccination should be enforced, like the already existing adolescent age anti-tetanus–diptheria–pertussis booster dose, or visits performed during sport activities.

Comparing the results of our 2005–06 survey with the 2004 national serosurvey, we found a higher seroprevalence of measles antibodies in our sample in the age group 2–9 years (table 2) with respect to the national data of the same age groups, probably due to a higher vaccination coverage in Tuscany in 2006 with respect to the national value of 2004.

In the age groups >15 years, we found comparable values, except for the 15–19 years age group, where the seropositive subjects in Tuscany were 60.3 vs. 71.8% at the national level. This difference is not statistically verifiable (for the national data only percentages are available for the age groups considered), but could be attributable to a lower measles virus circulation in Tuscany in the last years, as confirmed by the low incidence data in the years before the survey was performed.

Conclusion

This survey allowed to discover pockets of susceptibility to rubella and measles in Tuscany, and to identify target populations for catch-up strategies of MMR vaccination. As specified in the NPMCRE, all regions should address vaccination strategies with priority to all susceptible women in childbearing age, during the post-partum days, with a special focus on immigrant women. Improvement in vaccination coverage in paediatric age groups (<15 years) contributed to reduce the risk of contracting measles in the population targeted by vaccination campaigns. Our study shows an increasing susceptibility to measles in young adults from 2003 to 2006 in Tuscany, which reflects the expected epidemiological shift of measles infection mean age towards older age groups. According to these remarks, we suggest to improve vaccination coverage especially in the population >15 years with strategies focused on these age groups.

Moreover, this study demonstrates that a combined approach which takes into account incidence of the disease, immunization coverage and serological surveys on the general population, can contribute to define the more appropriate vaccination strategies in order to reach elimination objectives.

Conflicts of interest: None declared.

Key points

- The implementation of the NPMCRE in Italy required an in-depth system of surveillance on measles and rubella cases and on the level of protection, at regional and national level
- This study was performed to verify the seroepidemiological profile of Tuscany population for measles and rubella after implementation of the Plan (thus complementing data on coverage in special vaccination campaigns in schools), and to compare results with previous surveys performed both at national and regional level
- The results are examined in a historical perspective that correlates the evolution of vaccination recommendations and coverage with the occurrence of outbreaks in the last years, showing that sero-epidemiological studies can be predictive of pockets of susceptibility in the population and consequent outbreaks of diseases.
- This survey allowed to find out, for the first time, groups of susceptible individuals in the general population and to suggest additional vaccination strategies in hard-to-reach subjects who are out of the routine vaccination offer, but still very important for overall population susceptibility.
- Our study could give interesting elements on how to perform the surveillance of measles and rubella circulation in all countries involved in elimination efforts.

References

Predicting intention to biobank: a national survey

Christine R. Critchley¹, Dianne Nicol², Margaret F.A. Otlowski², Mark J.A. Stranger²

1 Faculty of Life and Social Sciences, Swinburne University, Hawthorn, Victoria, Australia
2 Faculty of Law, University of Tasmania, Hobart, Tasmania, Australia

Correspondence: Christine R. Critchley, Faculty of Life and Social Sciences, Swinburne University, P.O. Box 218, Hawthorn, Victoria, 3122, Australia, tel: +61 39214 5480, fax: +61 39819 0574, e-mail: ccritchley@swin.edu.au

Background: The success of human population biobanks are dependent on the publics’ willingness to participate. This research aimed to determine those factors important in determining the public’s intention to donate a biological sample to a publicly funded biobank, and allow that sample to be linked with medical records. Methods: A national sample of 1000 Australians was surveyed via telephonic interviews. Questions included the reported likelihood that respondents would participate in biobank research, ratings of trust in biobanks, beliefs that biobank research will lead to improved health care and general ratings of comfort with blood taking and DNA analysis. Results: The sample reported a high level of trust in university biobanks, a strong belief that biobank research will lead to improved health care and a strong willingness to participate in biobank research. Using structural equation modelling, trust in the biobank was found to be the most important determinant of intention to participate in biobank research, followed by general comfort with blood taking and DNA analysis, belief in health-care benefits and higher education. Gender, age, parental status and experience of genetic conditions were not significantly associated with intention to participate. Conclusions: Australians are generally willing to participate in biobank research, and this is strongly determined by trust. While benefit beliefs and comfort with research are also relevant, higher trust was associated with intention regardless of these factors, suggesting reasons other than concern for improved health care are important in determining the publics’ willingness to participate in biobank research.

Introduction

Human biobanks are repositories containing biological samples and genetic, medical and other personal data. The main purpose of creating biobanks is to link these information sources and making them available for use in research aimed at enhancing our understanding of medical conditions for translation into improvements in diagnosis, prevention and treatment. The linked information becomes a biobank resource that can be used for various research projects and can be accessed by multiple researchers. Largely as a result of these unique features, biobanks also present serious legal, social and ethical challenges that could significantly undermine their potential.¹²

Identifying the possible barriers to public participation in biobanking is vital to determining the kinds of biobanks and governance structures that are likely to succeed. Yet research identifying these barriers is scarce, with only a few studies directly investigating predictors of intention. National surveys from Sweden, Ireland, the UK and the USA all find a range of factors important in determining the willingness to participate, including: perception that the research will be beneficial,³⁴ general support for medical or genetic research,³⁴ general trust in scientific actors³ (i.e. researchers, research organizations), a history of blood donation,³ increased age,³⁵ gender,⁶ education,⁴ experience with a genetic condition⁴ and being a parent.⁴

Public trust⁷ is likely to be fundamental for the success of biobanks.⁸¹⁰ Trust is emerging as an important predictor in determining intention to participate in biomedical research: higher trust in scientific and medical authorities has been shown to be associated with increased intention to participate.³⁹ There are however, no published studies that specifically examine the determinants of trust and the relationship between trust and intention to participate in a biobank. Biobanks raise issues that are salient for all potential participants in biomedical research, including privacy, consent, allowing third-party access and commercialization, but these issues are heightened for participants in biobanks.¹⁰ Due to the long-term nature of biobank research, it will not be possible at the time of recruitment to provide specific information to participants on how their biological samples and information will be used in the future, and who will have access to them. This uncertainty is likely to activate a trust heuristic specifically related to the biobank, where potential participants will seek to understand, or at least gain an impression of, this relatively unfamiliar organization’s ability to protect their interests as well as advance biomedical discoveries.

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