



Summary Vision Screening Data: Germany

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Paolo Mazzone¹, Dr Jill Carlton², Dr Helen Griffiths³

1. Research Assistant, School of Health and Related Research, University of Sheffield, United Kingdom (UK)
2. Senior Research Fellow, School of Health and Related Research, University of Sheffield, United Kingdom (UK)
3. Senior Lecturer, Academic Unit of Ophthalmology and Orthoptics, University of Sheffield, United Kingdom (UK)

*Information provided by Dr Heike Elflein, Ophthalmologist, University Medical Centre,
Johannes Gutenberg University Mainz, Germany*

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1 Glossary of Terms: Vision Screening

Abnormal test result	A test result where a normal “pass” response could not be detected under good conditions. The result on screening equipment may indicate “no response,” “fail,” or “refer.”
Attendance rate	<p>The proportion of all those invited for screening that are tested and receive a result:</p> <ul style="list-style-type: none"> • Invited for screening includes all those that are offered the screening test. • Tested and receive a result could be a “pass” or “referral to diagnostic assessment”. <p>Attendance rate provides information on the willingness of families to participate in screening.</p>
Compliance with referral (percentage)	<p>The percentage of those who are referred from screening to a diagnostic assessment that actually attend the diagnostic assessment.</p> <p>Percentage of compliance provides information on the willingness of families to attend the diagnostic assessment after referral from screening.</p>
Coverage	<p>The proportion of those eligible for screening that are tested and receive a result:</p> <ul style="list-style-type: none"> • Eligible for screening includes those within the population that are covered under the screening or health care programme. • Tested and receive a result could be a “pass” or “refer to diagnostic assessment”. <p>Factors such as being offered screening, willingness to participate, missed screening, ability to complete the screen, and ability to document the screening results will influence the coverage.</p>
False negatives	<p>The percentage of children with a visual deficit (defined by the target condition) that receive a result of “pass” during screening.</p> <p>Example: If 100 children with visual deficit are screened, and 1 child passes the screening, the percentage of false negatives is 1%.</p>



False positives	The percentage of children with normal vision that are referred from screening to a diagnostic assessment.
Guidelines	Recommendations or instructions provided by an authoritative body on the practice of screening in the country or region.
Vision screening professional	A person qualified to perform vision screening, according to the practice in the country or region.
Inconclusive test result	A test result where a normal “pass” response could not be detected due to poor test conditions or poor cooperation of the child.
Invited for screening	Infants/children and their families who are offered screening.
Outcome of vision screening	An indication of the effectiveness or performance of screening, such as a measurement of coverage rate, referral rate, number of children detected, etc.
Untreated amblyopia	Those children who have not received treatment for amblyopia due to missed screening or missed follow-up appointment.
Persistent amblyopia	Amblyopia that is missed by screening, or present after the child has received treatment.
Positive predictive value	<p>The percentage of children referred from screening who have a confirmed vision loss.</p> <p>For example, if 100 babies are referred from screening for diagnostic assessment and 10 have normal vision and 90 have a confirmed visual defect, the positive predictive value would be 90%.</p>
Prevalence	The percentage or number of individuals with a specific disease or condition. Prevalence can either be expressed as a percentage or as a number out of 1000 individuals within the same demographic.
Programme	An organised system for screening, which could be based nationally, regionally or locally.
Protocol	Documented procedure or sequence for screening, which could include which tests are performed, when tests are performed, procedures for passing and referring, and so forth.
Quality assurance	A method for checking and ensuring that screening is functioning adequately and meeting set goals and benchmarks.
Referral criteria	A pre-determined cut-off boundary for when a child should be re-tested or seen for a diagnostic assessment.
Risk babies / Babies at-risk	All infants that are considered to be at-risk or have risk-factors for vision defects/ophthalmic pathology according to the screening programme.



	Two common risk factors are admission to the neonatal-intensive care unit (NICU) or born prematurely. However, other risk factors for visual defects may also be indicated in the screening programme.
Sensitivity	<p>The percentage of children with visual defects that are identified via the screening programme.</p> <p>For example, if 100 babies with visual defects are tested, and 98 of these babies are referred for diagnostic assessment and 2 pass the screening, the sensitivity is 98%.</p>
Specificity	<p>The percentage of children with normal vision that pass the screening.</p> <p>For example, if 100 babies with normal vision are tested, and 10 of these babies are referred for diagnostic assessment and 90 pass the screening, the specificity is 90%.</p>
Target condition	The visual defect you are aiming to detect via the screening programme.
Well, healthy babies	Infants who are <i>not</i> admitted into the NICU or born prematurely (born after a gestation period of less than 37 weeks).



2 Abbreviations

ACT	Alternating Cover Test
AR	Autorefraction
AS	Automated Screening
CT	Cover Test
CV	Colour Vision
EI	Eye Inspection
EM	Eye Motility
Fix	Fixation
GDP	Gross Domestic Product
GP	General Practitioner
Hir	Hirschberg test
NICU	Neonatal-intensive care unit
PM	Pursuit Movements
PPP	Purchasing Power Parity
PR	Pupillary Reflexes
RE	Retinal Examination
ROP	Retinopathy of Prematurity
RR	Red Reflex Testing
SV	Stereopsis
VA	Visual Acuity
WHO	World Health Organisation



3 Population and Healthcare Overview

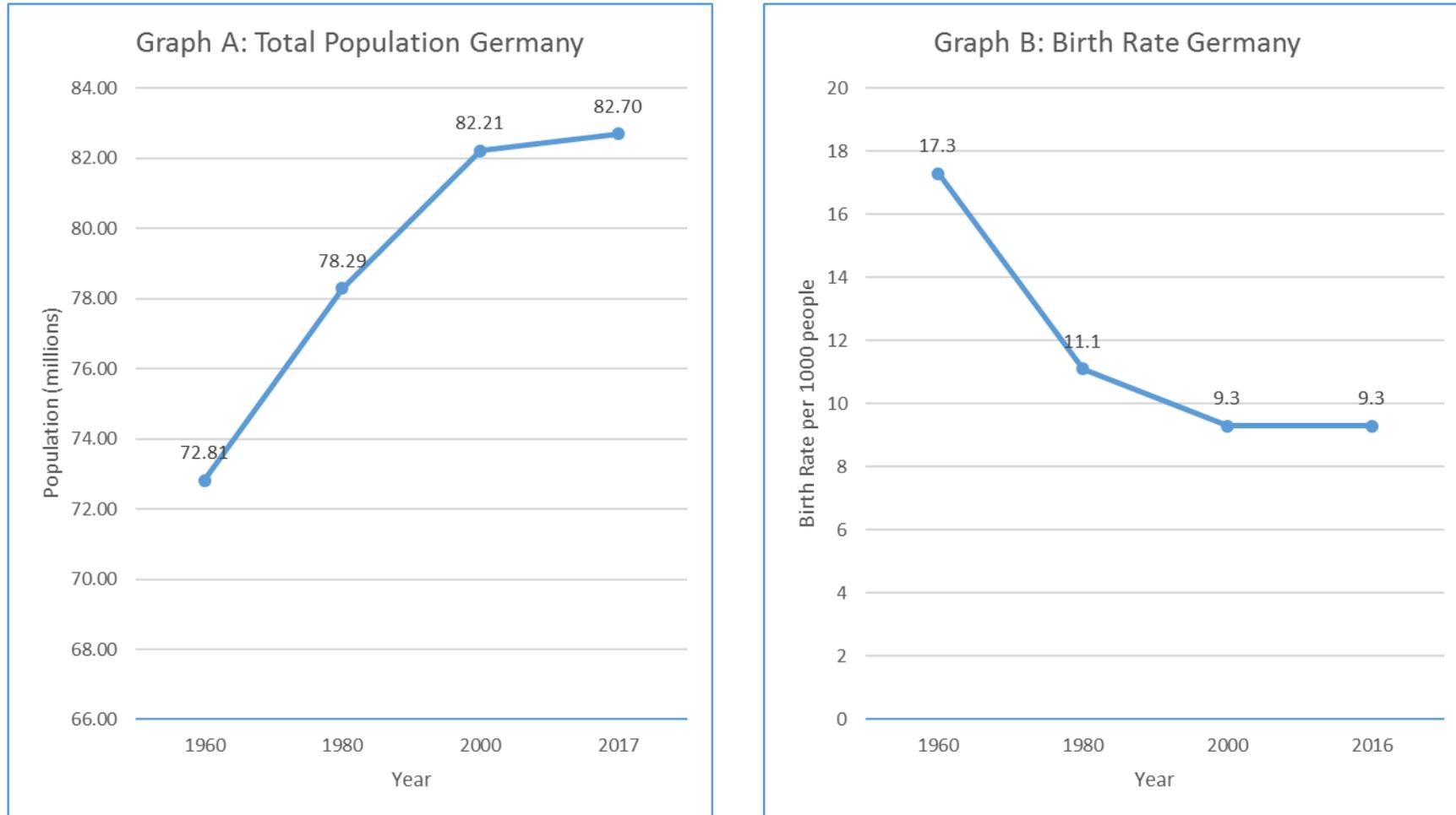
The population of Germany is 82,695,000 (World Bank, 2018a) and the birth rate is estimated at 9.3 births/1,000 population in 2016 (World Bank, 2018b). The change in population and birth rate from 1960 to 2017 is shown in Figure 1, graphs A and B respectively.

Germany has a reported population density of 237 people per square kilometre in 2017 and this has risen from 210 people per square kilometre in 1961 (World Bank, 2018c). Infant mortality in 2017 is estimated at 3.1 deaths/1,000 live births in total (World Bank, 2018d).

The average life expectancy in Germany is estimated at 80.6 years (World Bank, 2018e), with a death rate of 11.2 deaths/1,000 population in 2016 (World Bank, 2018f). Germany has a gross national income per capita (PPP int. \$, 2013) of \$44,000 (WHO, 2016). The estimated total expenditure on health per capita in 2014 was \$5,182 (Intl \$) and the total expenditure on health in 2014 as percentage of GDP was 11.3% (WHO, 2016).



Figure 1: Change in the Total Population and Birth Rate in Germany between 1960 and 2017



Source: Information sourced from World Bank (2018)



4 Vision Screening Commissioning and Guidance

In Germany, vision screening is embedded into a general preventative child healthcare screening system and is organised nationally, with no regional variation in vision screening. There are however, regional differences between paediatricians in relation to amblyopia screening (refraction measurement) for children aged up to 2 years. These differences depend on the type of health insurance individuals have; some reimburse the cost of screening, some do not. Some insurance covers a refraction examination at age 2 to 3 years. Approximately 10% of the general population of Germany have some form of private health insurance. Refraction screening is offered by some statutory and some private health insurances. In all regions of Germany vision screening is funded by the state for general health screening, but parents can opt to pay for additional screening, or if they are covered by private health insurance, they can attend vision screening through this. For example, refraction measurement is not part of the general vision screening in Germany, which is funded by the state (statutory and private health insurances have to pay for the general vision screening).

The vision screening programme started in the 1970s and the content was decided upon by the national government. The vision screening programme was changed in July 2008, whereby a visual acuity test was added as part of the general child healthcare examinations at the age of 3 years. There is no clear process in place to determine how often and the procedure adopted for revisions to the vision screening programme.

There are national general health screening guidelines, but no specific vision screening guidelines are available. There are no methods for quality monitoring imposed by the government. There has been research concerning vision screening in Germany, as part of health service research. Studies have been conducted to evaluate the outcome of vision screening; some of these studies are discussed in sections 6 of this report. Cost-effectiveness has been investigated by Gandjour et al (2003) which suggested that in Germany, both from a cost-effectiveness and clinical-effectiveness point of view, screening all children, up to the age of 1 year, for amblyopia and amylogenic factors, should be conducted by an ophthalmologist. However, the full text research article is not accessible, therefore all cost information in section 9 has been provided by the country representative.

Vision screening is conducted by paediatricians, medical assistants and nurses. Vision screening at the school entry examination is conducted by medical assistants, of which there are approximately 780 per million overall population. There are 179 paediatricians per million population and 12 physicians, however, this is overall and they are not just employed for vision screening. Nurses and practice assistants perform most screening, as delegated by the paediatrician. There is no specific training to perform vision screening.



5 Screening programme

The target conditions screened for by vision screening are retinopathy of prematurity (ROP), congenital eye disorders and reduced visual acuity. The health care professionals delivering vision screening, venue for screening and tests used vary depending on the age of the child as shown in Tables 1, 2 and 3 respectively. Specific details of the screening offered within each age group are described more fully in sections 5.1 to 5.4 below.

5.1 Vision screening - Preterm babies

Preterm babies up to the age of 3 months are screened by either an ophthalmologist or paediatrician in a hospital (during their hospital stay) and then at a private practice. The tests conducted at this age include eye inspection, red reflex testing and retinal examination. Preterm babies below 1500g and below 32 weeks of gestational age receive a retinal examination every two weeks (if nothing is found), until they reach normal birth term, in addition to this, they receive eye inspection and red reflex tests at days 3 to 10 and weeks 4 to 5.

5.2 Vision screening - Birth to 3 months

Well, healthy babies up to the age of 3 months are screened by a paediatrician in private practice. The tests conducted at this age include eye inspection and red reflex testing. These tests are conducted at 3 to 10 days and 3 months (eye inspection) and 4 weeks to 3 months (red reflex test). Babies are referred to an ophthalmologist for further diagnostic examination after the first abnormal test, there is no protocol for how many inconclusive tests determine referral for further examination.

5.3 Vision screening - 3 months to 36 months

Infants aged 3 to 36 months of age are screened by a paediatrician in private practice. The tests conducted at this age are eye inspection, fixation, red reflex testing, pursuit movements and pupillary reflexes and autorefraction (Rodenstock Vision Tester-R11 or R2). The tests performed at each age are:

- 3 to 4 months of age - eye inspection, red reflex testing and fixation
- 6 months - eye inspection, red reflex testing, fixation, pursuit movements
- 1 year - eye inspection, red reflex testing, fixation, pursuit movements, pupillary reflexes
- 2 years - eye inspection, red reflex testing, pupillary reflexes

If a child is on private health coverage and in some health insurances, automated screening (PlusOptix) can be conducted at age 1 year and 3 years. One abnormal test determines referral to an ophthalmologist for further examination.



5.4 *Vision screening - 36 months to 7 years*

Children aged 36 months up to 7 years are screened by a paediatrician in private practice. The tests conducted at this age include eye inspection, Hirschberg test, pupillary reflexes, visual acuity measurement and stereopsis (Lang Test). Tests are conducted at 4 years of age, 5 years of age and by a nurse under the guidance of a paediatrician before entering school at 6 years of age. Visual acuity is measured at all ages by a paediatrician or the medical assistant under supervision of the paediatrician. The Löhlein chart is the most commonly used chart, although there are no specific guidelines detailing the use of this. The Löhlein chart is based on the Snellen principle, but optotypes are presented. The optotypes sizes and visual acuity ranges from 0.2 to 1.0 decimal (0.7 to 0.0 logMAR, 6/30 to 6/6 Snellen). There are no formal defined referral criteria per age category. One abnormal test determines referral to an ophthalmologist for further examination.



Table 1: Healthcare professionals who conduct vision screening in each age group

Table 1	Ophthalmologist	Paediatrician	Medical Assistant <i>Under supervision of paediatrician</i>	Nurse <i>Under supervision of paediatrician</i>
Preterm babies	✓	✓	×	×
0 to 3 months	×	✓	×	×
3 to 36 months	×	✓	×	×
3 to 7 years	×	✓	✓	✓



Table 2: Vision screening tests used in vision screening for each age group

Table 2	EI	Fix	RR	RE	Hir	PM	PR	VA	SV	AR	AS <i>with health insurance</i>
Preterm babies	✓	✗	✓	✓	✗	✗	✗	✗	✗	✗	✗
0 to 3 months	✓	✗	✓	✗	✗	✗	✗	✗	✗	✗	✗
3 to 36 months	✓	✓	✓	✗	✗	✓	✓	✗	✗	✓	✓
3 to 7 years	✓	✗	✗	✗	✓	✗	✓	✓	✓	✗	✓

Key: EI: Eye Inspection; Fix: Fixation; RR: Red Reflex Testing; Hir: Hirschberg; RE: Retinal Examination; PM: Pursuit Movements; PR: Pupillary Reflexes; VA: Visual Acuity Measurement; SV: Stereopsis; AR: Autorefraction; AS: Automated Screening



Table 3: Location of vision screening for each age group

Table 3	Hospital	Private Practice
Preterm babies	✓	✓
0 to 3 months	×	✓
3 to 36 months	×	✓
3 to 7 years	×	✓



6 Automated Screening

Automated vision screening is achieved using handheld, portable devices designed to detect presence of refractive error from 6 months of age. It provides objective results of refraction and is used to detect amblyopic risk factors. This differs from other methods used to screen children for amblyopia which focus on detection of the actual condition and the resulting visual loss. In Germany, the automated screening devices used include, most commonly, PlusOptix. It is not known how much these devices cost, the maintenance costs per year, or after how many years they are scheduled to be replaced.

It is not known how many of these areas are conducting automated screening. The age at which it is used depends on the health insurance and whether or not the cost of this is reimbursed. The Rodenstock Vision Tester device is presumed to be widely used in Germany, as it is used in the preschool health examination vision testing. In general, visual acuity is tested alongside autorefraction, however, in younger children (preschool) visual acuity is not included. It is not known if this is used on all children, or just a selected group where visual acuity is borderline or failed.

The referral criteria depend on age; the current cut-off values are: up to the age of 90 months: anisometropia ≥ 1.0 Dioptres. It is not known if a child is still referred if he/she passes the visual acuity test, but fails autorefraction. There is no comparative data between areas that do and do not perform automated screening.



7 Provision for Visually Impaired

In Germany, there are 74 registered schools for blind or severely visually impaired children with 4,615 children attending these schools. The costs per child for these school is not known. There is special support for visually impaired children who attend regular mainstream primary school, however, this depends on the local situations and the integration of the headmaster/teachers. There are no legal criteria for special support offered to them and the costs are not known.

8 Knowledge of existing screening programme

8.1 Prevalence/Diagnosis

There is no countrywide data concerning the prevalence of treated or untreated amblyopia at age 7 years. The prevalence of persistent amblyopia (missed by screening or failed treatment) at age 7 years is unknown. However, a study by Elflein et al (2015) found a prevalence of 5.6% in adults age 35-44 years. This was based on a population of 3227 participants from the city of Mainz and the Mainz-Bingen area. A questionnaire issued to 17,640 parents of children and adolescents aged up to 17 years living in Germany found the reported prevalence of strabismus to be 4.1%. (Schuster et al, 2017). In this study, prevalence was further stratified by age:

- 0-1 years: 2.6% – Confidence Interval (CI): 1.8-3.6
- 2-3 years: 2.3% – CI: 1.6 to 3.5
- 4-5 years: 3.3% – CI: 2.5 to 4.3
- 6-7 years: 4.1% – CI: 3.2 to 5.2

There is no available evidence pertaining to the incidence of the four types of amblyopia (strabismic, refractive, combined mechanism and deprivation).

8.2 Coverage

All children are invited for vision screening as part of the general screening. Children are sent a letter and invited by the state for general preventative child healthcare screening. There is no national data on coverage of vision screening. A study by Kamtruiris et al (2007) carried out a retrospective survey to determine the uptake of child screening examinations. Participants consisted of 17,641 parents of children and adolescents up to age 17 years. The results indicated that up to 3-years of age) 90% attended the screening, however this decreased to 89.0% at 4-years of age, and 86.4% for screening offered at 5 years of age

8.3 Screening evaluation

There is currently no data available concerning the percentage of false negative screening results, false positive screening results, the positive predictive value of a 'refer' result, the sensitivity, or specificity of vision screening in Germany.

8.4 Treatment success

There is no available data regarding the percentage of infants treated for congenital eye disorders in the total population. The percentage of children treated for strabismus, after being screened before the age of seven is unknown, however Schuster et al (2017) report that 5% of children have strabismus in Germany (Baseline survey 2003 to 2006; N=17,640; 0-17 years of age). The percentage of all children treated for strabismus before the age of 7 years



in unknown. The percentage of children treated for amblyopia, after being screened before the age of 7 years, is not known. The percentage of all children treated for amblyopia is also not known. There is no registration or documentation of noncompliance with referral after an abnormal screening test result. It is estimated that 750 patients have childhood cataract surgery and undergo surgery each year throughout the country.

Ophthalmologists are the only professionals who prescribe glasses to children under the age of 7 years, after referral from vision screening. Other treatment options include patching, cataract surgery and glaucoma treatment, where appropriate. All eligible children are offered treatment.



9 Costs of vision screening in children

9.1 Cost of vision screening

The salary costs per year for vision screening professionals is not known. However, the salary costs per hour for screening professionals is estimated at 41.79 Euros for each child healthcare examination lasting approximately 30 minutes: 21 Euros of which is reflective of the time take for the vision screening. It is estimated that it costs approximately 110,000 Euros to train a paediatrician, between leaving secondary education to qualification. The total screening costs per year are not available. The total costs per child, per year, for vision screening nationally are estimated at:

- Amblyopia screening (PlusOptix) when carried out at age 1 year and age 3 years = 25 Euros
- Vision screening as part of the general health examination carried out at age 3 years, 4 years and 5 years of age and vision screening at school entry health examination = 13.50 Euros

9.2 Cost of treatment for amblyopia

The estimated total costs of treatment for typical patients with refractive amblyopia and strabismic amblyopia, including follow up are 1,440 Euros:

- cost of visits: 30 Euros at 2 per year, over 4 years = 240 Euros
- cost for glasses: 200 Euro per year (estimation) x 4 years = 800 Euros
- cost for patching: 100 Euro per year (estimation) x 4 years = 400 Euros

9.3 Cost of Treatment for strabismus

The estimated costs of strabismus surgery, including follow up are not known.

9.4 Cost of treatment for cataract

The estimated costs of congenital cataracts surgery, including follow up of deprivation amblyopia are 6,000 Euros:

- cataract surgery 2x approximately (2,000 Euros)
- ophthalmologist appointments: 20 visits at 30 Euros each visit, patching 400 Euros, glasses/contact lenses 1000 Euros

Vision screening is mostly covered by health insurance, some paediatricians offer uncovered PlusOptix screening for amblyopia, parents can choose to pay for this (25 Euros). There is no financial reward for attending vision screening and no penalty for non-attendance. Vision screening is obligatory and enforced through school entry screening and the national child healthcare screening system.

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