

Supplementary Material

Supplement to Karl et al., Costs of Public Health Screening of Children for Presymptomatic Type 1 Diabetes in Bavaria, Germany

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Table S1. Overview of the amount of resources/estimated units per child screened in the Fr1da study

Index Figure 1	Time spent (minutes), Pediatric practice [§]	Mean	SD	Distribution	Explanation (see Supplementary Material, Online survey for paediatricians)	Source
d	Consent (physician time)	5.14	1.90	Gamma moments	Survey question #3	A
e	Capillary blood draw					
	% by pediatrician	23.08%		Beta	Survey question #4	A
	Physician time	4.00	1.75	Gamma moments	Survey question #4.1	A
	% by nurse	76.92%		Beta	Survey question #4	A
	Nurse time	3.73	0.97	Gamma	Survey question #4.1	A
f	Packaging					
	% by pediatrician	5.88%		Beta	Survey question #5	A
	Physician time	4.90	2.00	Gamma moments	Survey question #5.1	A
	% by nurse	94.12%		Beta	Survey question #5	A
	Nurse time	4.90	2.00	Gamma	Survey question #5.1	A
m	Venous blood draw					
	% by pediatrician	87.88%		Beta	Survey question #7	A

	Physician time	6.61	2.80	Gamma moments	Survey question #7.1	A
	% by nurse	12.12%		Beta	Survey question #7	A
	Nurse time	7.35	0.76	Gamma	Survey question #7.1	A
o	Communication of negative screening result					
	% overall	18.06%	23.00%	Beta moments	Survey question #8	A
	% by pediatrician	88.55%		Beta	Survey question #8.1	A
	Physician time	4.32	2.31	Gamma moments	Survey question #8.2	A
	% by nurse	11.45%		Beta	Survey question #8.1	A
	Nurse time	2.08	1.11	Gamma	Survey question #8.2	A
p	Communication of positive screening result					
	% by pediatrician	97.76%		Beta	Survey question #9	A
	Physician time	11.18	3.07	Normal	Survey question #9.1	A
	% by nurse	2.24%		Beta	Survey question #9	A
	Nurse time	3.00	0.75	Normal	Survey question #9.1	A

Index Figure 1	Time spent (minutes), Coordination center and laboratory	Mean	SD	Distribution	Explanation	Source
a	Logistics					
	Data management time (per child)	1.67	0.33	Normal	A data manager worked 8 hours (sd = 1.6 hours) per week from February 2015 to May 2019 for the Fr1da study	C
	Packing packages with forms and other materials for pediatricians	0.12	0.02	Normal	The time it took to pack one package (12 minutes [sd = 2.4 minute]) that include starter packages for 100 children	C
	Hotline time (per child included)	1.11	0.22	Normal	Fr1da offered a hotline for participating pediatricians that has been active for 90 minutes (sd = 18 minute) per day for 1581 weekdays from February 2015 to May 2019	C
h	Processing					
	Centrifuging	3.25	0.45	Normal	The time per centrifuge (240 min) divided by the number of samples per day (73.91).	B
	Data entering	2.00	0.40	Normal	Basic information had to be entered for every sample received	B
	Follow-up calls (per sample)	0.20	0.02	Normal	The time spent on follow-up calls per day (15 min) divided by the number of samples per day (73.91)	B
i	3-Screen ELISA	3.79	0.38	Normal	The time per ELISA duration (280 min) divided by the number of samples per day (73.91).	B
	Interpretation of ELISA results	0.07	0.01	Normal	Results of every sample that had been tested with ELISA were reviewed by a laboratory staff member	B

j	GADA, IA-2A, ZnT8A (RBAs)	5.68	0.57	Normal	The time per RIA duration (420 min) divided by the number of samples per day (73.91).	B
k	IAA	6.49	0.65	Normal	The time per IAA (480 min) divided by the number of samples per day (73.91).	B
l	Results review	1.00	-	-	For every sample that had been tested positive for at least one autoantibody a medical expert and two technical staff members had to review the result	B

Index Figure 1	Materials used (number per child)	Units	SD	Distribution	Explanation	Source
a	Cardboard used per package sent to pediatricians	0.01	-	-	Packages to doctors were send in cardboard packaging and included material for 100 children	C
a	Flyer and consent form	1.00	-	-	Flyers and consent forms that were send to the pediatricians offices	C
a	Postage (materials to pediatricians) per child	0.01	-	-	The postage for one package with materials (e.g. flyer, consent forms, lancets) for 100 children	C
b	Blood collection devices	1.00	-	-	Lancets & tubes	C
c	Postage (samples to laboratory), mean units	0.23	0.15	Normal	One package can contain more than one sample. Therefore, one package is divided by the number of samples sent per week	C
g	Postage (resend request)	1.00	-	-	Postage for one resend request	C
h	Lab materials	1.00	-	-	Pipette tips and serum tubes	C
h	Barcodes	5.00	-	-	For every sample the laboratory used five barcodes	C
i	3-Screen ELISA	1.00	-	-	Number of tests per sample	C

j	GADA, IA-2A, ZnT8A (RBAs)	1.00	-	-	Number of tests per sample	C
k	IAA	1.00	-	-	Number of tests per sample	C
n	Postage (positive result communication to pediatrician)	1.00	-	-	Postage for the communication of one positive result (negative results were communicated via email)	C
Index Figure 1	Measures carried out (number per child), Local diabetes clinics	Units			Explanation	Source
q	OGTT	1.00	-	-	To stage one child at the local diabetes clinic a OGTT is performed	C
q	HbA1c	1.00	-	-	To stage one child at the local diabetes clinic HbA1c% is measured	C
r	Education	1.00	-	-	Every participating family receives one initial education	C
	Number of samples	Mean	SD	Distribution	Explanation	Source
	Samples sent per week (pediatrician to laboratory)	3.50	1.81	Gamma	Survey question #1	A
	Samples received per day by laboratory	73.91	22.18	Normal	Documentation of the Fr1da coordination center	C

Note. 3-Screen ELISA = 3-Screen Islet Cell Antibody ELISA (RSR Ltd., Cardiff, UK) measuring autoantibodies to GAD (GADA) and/or insulinoma-associated antigen-2 (IA-2A) and/or zinc transporter-8 (ZnT8A); RBA = radio binding assay; IAA = insulin autoantibodies; OGTT = oral glucose tolerance test; HbA1c = glycated hemoglobin; § all pediatrician time estimates are 75% of what the actual questionnaire responses were; A = online survey among 134 participating pediatricians; B = information based Fr1da staff member documentation; C = Fr1da coordination center and laboratory

Table S2. Estimated costs per unit of resources

Costs per unit	Observed		Distribution	Explanation	Source
	Mean	SD			
Pediatrician time costs	€2.48	€0.05	Normal	Annual revenue of pediatrician in a practice: €352,000 Standard deviation of annual revenue: 2.0% Average working day per year: 214 Average hours per week: 49 Minus the average annual income of a nurse plus employer contributions §	(1)
Nurse time costs	€0.39	€0.08	Normal	Annual income: €32,749.62 Standard deviation of annual income: 20% Working day according pediatrician working days: 214 Average hours per week: 40 Plus employer contributions for pension insurance (9.3%), health insurance (7.3%), unemployment insurance (1.2%), nursing care insurance (1.6%).	(2)
Laboratory staff member time costs	€0.46	€0.09	Normal	Annual income: €39,310.85 Standard deviation of annual income: 20% Working day according pediatrician working days: 214 Average hours per week: 40 Plus employer contributions for pension insurance (9.3%), health insurance (7.3%), unemployment insurance (1.2%), nursing care insurance (1.6%).	(3)
Expert time costs	€2.48	€0.05	Normal	Equal to the pediatrician time costs.	(1)
Scientific staff member time costs	€0.71	€0.14	Normal	Annual income: €59,950.67 Standard deviation of annual income: 2.0% Working day according pediatrician working days: 214 Average hours per week: 40 Plus employer contributions for pension insurance (9.3%), health insurance (7.3%), unemployment insurance (1.2%), nursing care insurance (1.6%)."	(4)

Cardboard	€1.77	-	-	Costs for cardboard for one package that contains material for 100 children	(5)
Costs for printing one set of forms	€0.14	-	-	Costs for printing one set of forms	(5)
Postage for large materials to pediatricians	€6.25	-	-	Postage for one package sent to a pediatrician practice that includes material for 100 children	(5)
Postage for smaller packages	€0.80	-	-	Postage for any other kind of smaller package or letter (e.g. resend requests, samples to laboratory)	(5)
3-Screen ELISA	€1.20	-	-		RSR Ltd.
GADA, IA-2A, ZnT8A (RBAs)	€5.50	-	-		(5)
IAA	€6.50	-	-		(5)
Blood collection devices	€0.18	-	-		(5)
Follow-up calls	€0.09	-	-		
Barcodes	€0.14	-	-		(5)
Other lab material	€0.04	-	-		(5)

OGTT	€14.17	-	-	Costs per OGTT were drawn from the uniform valuation standard of the EBM	(6)
HbA1c	€4.00	-	-	Costs per HbA1c measurement were drawn from the uniform valuation standard of the EBM	(6)
Diabetes Education	€33.00	-	-	Costs per education were drawn from the uniform valuation standard of the EBM	(6)

Note. 3-Screen ELISA = 3-Screen Islet Cell Antibody ELISA (RSR Ltd., Cardiff, UK) measuring autoantibodies to GAD (GADA) and/or insulinoma-associated antigen-2 (IA-2A) and/or zinc transporter-8 (ZnT8A); RBA = radio binding assay; IAA = insulin autoantibodies; OGTT = oral glucose tolerance test; HbA1c = glycated hemoglobin; EBM = uniform evaluation standard of the National Association of Statutory Health Insurance Physicians (KBV); [§] To estimate the time costs per minute for a pediatrician in Germany, we relied on the “Zi-Praxis-Panel” (1). The panel conducts an annual survey of physicians in private practice in Germany. The survey collected data from 5,519 physicians including 107 pediatricians and analyzed detailed information on physician income/revenue and expenditures. As a result, we were able to determine the actual income of pediatricians in the survey. We divided these incomes by reported minutes worked, assuming a reported workload of 49 hours per week, 251 days worked, and 37 days absent due to vacations and illness. To avoid double-counting, the income of a nurse has been deducted from the annual revenue of the practice. Physicians in private practice are usually self-employed. Nurses and healthcare staff are usually employed and therefore employer contributions (overhead costs) apply.

Table S3. Cost items and average costs per measure in the Fr1da study

Index Figure 1	Cost item	Costs per measure	Probabilistic 95% confidence interval		Calculation	
		Mean	LCI	UCI	Number of units per child (see Table S1)	Costs per unit (see Table S2)
a	Logistics	€2.57	€1.93	€3.17	Units of cardboard	Costs per cardboard packaging
					Units of forms per family	Costs per form
					Time it takes to pack one material package / 100	Laboratory staff member time costs
					Time it takes to manage the data of one child	Scientific staff member time costs
b	Lancet & tube	€0.18	-	-	Number of blood collection devices	Costs of one blood collection device
c	Postage	€0.23	€0.03 [§]	€0.53	1 / Samples per week (physician to laboratory)	Postage for one small package
d	Consent	€12.77	€5.14	€24.37	Time it takes a pediatrician to inform families and obtain their consent	Pediatrician time cost
e	Capillary blood	€3.40	€1.66	€6.00	(% of capillary blood samples performed by a pediatrician * time it takes a pediatrician to perform a capillary blood draw)	Pediatrician time cost
					(% of capillary blood draws performed by a nurse * time it takes a nurse to perform a capillary blood draw)	Nurse time cost

f	Packaging	€0.72	€0.10	€1.25	(% of packaging performed by a pediatrician * time it takes to pack samples)	Pediatrician time cost
					(% of packaging performed by a nurse * time it takes to pack samples) / samples per week (physician to laboratory)	Nurse time cost
g	Sample request	€0.80	-	-	Resend request	Postage for one resend request
h	Processing	€2.70	€1.97	€3.53	Time spent on follow-up calls per sample	Laboratory staff member time costs
					Time spent on centrifuging / samples received per day by laboratory	Laboratory staff member time costs
					Number of barcodes	Costs of one barcode
					Number of other lab materials	Costs of one unit of pipette tips and serum tubes
					Data entering	Laboratory staff member time costs
i	3-Screen ELISA	€2.98	€2.23	€3.82	Time spent on ELISA / samples received per day by laboratory	Laboratory staff member time costs
					Number of ELISA tests utilized per sample	Costs of one measurement of ELISA
					Time spent on interpreting ELISA result	Laboratory staff member time costs
j	GADA, IA-2A, ZnT8A (RBAs)	€8.13	€7.07	€9.30	Time spent on RBAs / samples received per day by laboratory	Laboratory staff member time costs
					Number of RBAs utilized per sample	Costs of one measurement of RBAs

k	IAA	€9.51	€8.27	€10.95	Time spent on IAA-RBAs / samples received per day by laboratory	Laboratory staff member time costs
					Number of RBAs utilized per sample	Costs of one measurement of IAA
l	Results review	€3.65	€3.31	€3.99	Time spent on interpretation of a laboratory result	Expert time costs
					Time spent on interpretation of a laboratory result	Laboratory staff member time cost
					Time spent on interpretation of a laboratory result	Scientific staff member time costs
m	Venous blood	€12.75	€5.80	€22.39	% of venous blood draws performed by a pediatrician * time it takes a pediatrician to perform a venous blood draw	Pediatrician time cost
					% of venous blood draws performed by a nurse * time it takes a nurse to perform a venous blood draw	Nurse time cost
n	Result communication (letter)	€0.80	-	-	Positive result letter	Postage for one letter
	Communication to family (negative result) (observed) [§]	€1.73	€0.36	€4.88	% of negative results communicated by a pediatrician * time it takes a pediatrician to communicate a negative result	Pediatrician time cost
					% of negative results communicated by a nurse * time it takes a nurse to communicate a negative result	Nurse time cost
o	Communication to family	€9.59	€2.53	€23.70	% of negative results communicated by a pediatrician * time it takes a	Pediatrician time cost

	(negative result) (routine)				pediatrician to communicate a negative result	
					% of negative results communicated by a nurse * time it takes a nurse to communicate a negative result	Nurse time cost
p	Communication to family (positive result)	€27.16	€26.76	€27.41	% of positive results communicated by a pediatrician * time it takes a pediatrician to communicate a positive result	Pediatrician time cost
					% of positive results communicated by a nurse * time it takes a nurse to communicate a positive result	Nurse time cost
q	Metabolic staging	€18.17	-	-	Number of OGTTs necessary for staging	Costs of one OGTT
					Number of HbA1c measurements necessary for staging	Costs of one HbA1c measurement
r	Diabetes Education	€33.00	-	-	Number of education sessions	Costs of one education session

Note. LCI = lower 95% confidence interval; UCI = upper 95% confidence interval; 3-Screen ELISA = 3-Screen Islet Cell Antibody ELISA (RSR Ltd., Cardiff, UK) measuring autoantibodies to GAD (GADA) and/or insulinoma-associated antigen-2 (IA-2A) and/or zinc transporter-8 (ZnT8A); RBA = radio binding assay; IAA = insulin autoantibodies; OGTT = oral glucose tolerance test; HbA1c = glycated hemoglobin; § costs observed for negative result communication are not displayed in Figure 1 because negative result communication was generally assumed in 16.1% of *all* negative results, e.g. also including ELISA negative results. § Due to the distribution parameters (mean = €0.23, sd = €0.15), some of the simulated values where < 0. These values have been replaced by the deterministic mean of €0.23.

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Online survey for pediatricians participating in the Fr1da study

1. On average, how many children participate in Fr1da in your practice per week?

Please give an integral number: |_|_|_|

2. What is the proportion of families that deny their participation in Fr1da after receiving information?

Please give an integral number: |_|_|_| %

3. On average, how much time does information and consent per family take?

Please give the time in minutes: |_|_|_|min

4. Usually, who performs the capillary blood draw that is necessary for participation in the Fr1da study?

0 Physician

0 Nurse

- 4.1. On average, how much time does a capillary blood draw take?

Please give the time in minutes: |_|_|_|min

5. Usually, who takes care of the packaging and shipping of the samples?

0 Physician

0 Nurse

- 5.1. On average, how much time does the packaging and shipping of the samples take?

Please give the time in minutes: |_|_|_|min

6. Usually, who informs families that a venous blood draw is needed for the child and asks for another appointment?

0 Physician

0 Nurse

- 6.1. On average, how much time does this conversation with families take?

Please give the time in minutes: |_|_|_|min

7. Usually, who performs the venous blood draw that is sometime requested by the in the Fr1da study coordination center?

0 Physician

0 Nurse

7.1. On average, how much time does a venous blood draw take?

Please give the time in minutes: |_|_|_|min

8. What is the proportion of families that you inform of a negative screening result (i.e. no diagnosis of presymptomatic type 1 diabetes)?

Please give an integral number: |_|_|_| %

8.1. Usually, if the families are informed of a negative screening result, who informs the families?

0 Physician

0 Nurse

8.2. On average, how much time does the communication of a negative screening result take?

Please give the time in minutes: |_|_|_|min

9. Usually, who informs the families of a positive screening result (i.e. diagnosis of presymptomatic type 1 diabetes)?

0 Physician

0 Nurse

9.1. On average, how much time does the communication of a positive screening result take?

Please give the time in minutes: |_|_|_|min

Fr1da Study Group

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