

Supplementary Table 1. Description of participating birth defects registries included in the omphalocele mortality study by registry type: coverage, years in study, ascertainment period, stillbirth definition, ETOPFA allowed and availability of prenatal screening services.

Country – Registry	Coverage	Years in study	Ascertainment period	Stillbirth definition	ETOPFA allowed	Prenatal screening services
Hospital-based registries						
Argentina – RENAC	N	2009-2014	hospital discharge	>500 g	No	Yes, but no official program
Colombia – Bogotá	R	2000-2014	1st day	>500 g	Yes, since 2006	Yes
Colombia – Cali	R	2011-2014	1st day	>500 g	Yes, since 2006	Yes
South America – ECLAMC	R ¹	1995-2014	hospital discharge	>500 g	No ¹	Yes
Spain – ECEMC	R ²	1995-2013	3 days	24 weeks or 500 g ¹	Yes, since 1985	Yes
Mexico – RYVEMCE	R	1978-2013	3 days	≥20 gestational weeks or ≥500 g	No	No
Iran – TROCA	R	2004-2012	1 year	20 weeks	Yes, restrictions since 2013	Yes
Israel – SMC	R ³	2000-2014	hospital discharge	Not included	Yes, but not registered	Yes
Population-based registries						
Czech Republic	N	1974-201	15 years	22 weeks or >500 g	Yes	Yes

Country – Registry	Coverage	Years in study	Ascertainment period	Stillbirth definition	ETOPFA allowed	Prenatal screening services
		4				
France – Paris	R	1981-2014	28 days	22 weeks	Yes	Yes
Germany - Saxony Anhalt	R	1980-2014	1 year	>500 g	Yes	Yes, since 1990
Italy – Lombardy	R	2003-2012	6 years	23 weeks	Yes	Yes
Italy – Tuscany	R	1992-2014	1 year	20 weeks	Yes	Yes
Malta – MCAR	N	1995-2013	1 year	22 weeks	No	Yes, gradually introduced
Netherlands – North	R	1981-2014	10 years	24 weeks	Yes	Yes, since 2007
Slovak Republic	N	2001-2013	hospital discharge	>500 g	Yes	Yes
Sweden	N	1999-2014	before '87 1 month, after '87 1 year	until 2006: 28 weeks, 2007 and after: 22 weeks	Yes, registration since 1999	Yes, since early 1980's
UK – Wales	R	1998-2014	18 years	24 weeks	Yes	Yes, since 2003
Ukraine - OMNI-	R	2000-	1 year	until 2006: 28	Yes	Yes

Country – Registry	Coverage	Years in study	Ascertainment period	Stillbirth definition	ETOPFA allowed	Prenatal screening services
Net		2013		weeks/>1000 g 2006 and after: 22 weeks/>500 g		
USA – Arkansas	S	1993-2012	2 years	20 weeks	Yes, until 20 weeks	Yes
USA – Atlanta	R	1974-2008	6 years	20 weeks	Yes ²	Yes
USA – Texas	S	1996-2012	1 year	20 weeks	Yes, until 20 weeks	Yes
USA – Utah	S	1997-2012	2 years	20 weeks	Yes	Yes

Coverage: N=National, R=regional, S=State-wide; ¹ While the registry encompasses several regions in South America, for this study only the hospitals providing information on terminations of pregnancy for fetal anomalies were included ² several regions in Spain currently covering around 18% of total births, ³referral area of one hospital, data only concern livebirths (no information available on stillbirths and terminations of pregnancy for fetal anomalies); **Still birth definition:** ¹if gestational age of death is not determined (since 1980); **ETOPFA allowed** ¹except for anencephaly. ²Elective terminations were ascertained from prenatal diagnostic sites beginning in 1994, prior to that they were only rarely ascertained from hospital records.
ECEMC= Spanish Collaborative Study of Congenital Malformations; ECLAMC=Latin American Collaborative Study of Congenital Malformations; ETOPFA=Termination of Pregnancy for Fetal Anomalies; MCAR=Malta Congenital Anomalies Registry; OMNI-Net=Ukraine Birth Defects Prevention Program; RENAC=National Network of Congenital Anomalies of Argentina; RYVEMCE= Mexican Registry and Epidemiological Surveillance of Congenital Malformations; TROCA=Tabriz Registry of Congenital Anomalies; SMC=Soroka Medical Center; UK=United Kingdom; USA=United States of America.

Supplementary Table 2. Follow-up methods used to determine vital status for children born with omphalocele from birth defects registries included in the study

Country-Registry	Years in study	Follow-up until discharge from the maternity hospital	Follow-up by a clinician or registry staff	Linkage with death certificates	Complete follow up until age	Maximum age at mortality reported in study
<i>Hospital-based registries</i>						
Argentina-RENAC	2009 - 2014	Yes	Yes	No	7 days	1-6 days
Colombia-Bogotá	2000 - 2014	Yes	Yes	Yes, until 48 hours of life	48 hours	<1 day
Colombia-Cali	2011 - 2014	Yes	Yes	Yes, until 48 hours of life	48 hours	No mortality reported for livebirths
South America-ECLAMC	1995 - 2014	Yes	Yes	No	7 days	28 days-11 months
Spain-ECEMC	1995 - 2013	Yes ¹	No	No	7 days	1-6 days
Mexico-RYVEMCE	1978 - 2013	Yes	No	No	7 days	1-6 days
Iran-TROCA	2004 - 2012	Yes	Yes ²	No	7 days	No mortality reported for livebirths
Israel-SMC	2000 - 2014	Yes	No	Yes, end 2014	-	<1 day
<i>Population-based registries</i>						
Czech Republic	1974 - 2014	No	No	Yes, end 2015	-	≥5 years
France-Paris	1981 - 2014	Yes	Yes	No	1 month	7-27 days
Germany-Saxony	1980	Yes	Yes ³	No	1 year	28 days-11 months

Country-Registry	Years in study	Follow-up until discharge from the maternity hospital	Follow-up by a clinician or registry staff	Linkage with death certificates	Complete follow up until age	Maximum age at mortality reported in study
Anhalt	- 2014					
Italy-Lombardy	2003 - 2012	No	No	Yes, at 31 Dec 2015	-	28 days-11 months
Italy-Tuscany	1992 - 2014	No	No	Yes, at 31 Dec 2015	-	7-27 days
Malta-MCAR	1995 - 2013	Yes ⁴	No	Yes, until age 1 year	1 year	28 days-11 months
Netherlands-Northern	1981 - 2014	Yes	Yes	No	1 year	28 days-11 months
Slovak Republic	2001 - 2013	Yes	No	No	1 month	7-27 days
Sweden	1999 - 2014	No	No	Yes, at 1 April 2016	-	≥5 years
UK-Wales	1998 - 2014	Yes	No	Yes, to GP system, till 18 years	18 years	1-4 years
Ukraine-OMNI-Net	2000 - 2013	Yes	Yes	No	1 year	28 days-11 months
USA-Arkansas	1993 - 2012	Yes	No	Yes, at 31 Dec 2015	-	≥5 years
USA-Atlanta	1974 - 2008	Yes	No	Yes, up to 2008	-	≥5 years
USA-Texas	1996 - 2012	Yes	No	Yes, 31 Dec 2013	-	≥5 years

Country-Registry	Year s in stud y	Follow- up until discharg e from the maternit y hospital	Follow -up by a clincia n or registr y staff	Linkage with death certificates	Comple te follow up until age	Maximum age at mortality reported in study
USA-Utah	1997 - 2012	Yes	No	Yes, until age 2 year	2 years	1-4 years

Follow up method for live births: ¹ the participating physicians in the program are especially focused on the ascertainment of birth defects; ²children in university hospital(s); ³ until 18 years; ⁴ babies are followed up until discharge and their hospital files are again seen at 1 year of age, linkage with mortality data continues indefinitely

ECEMC= Spanish Collaborative Study of Congenital Malformations; ECLAMC=Latin American Collaborative Study of Congenital Malformations; GP=General Practitioner; MCAR=Malta Congenital Anomalies Registry; OMNI-Net=Ukraine Birth Defects Prevention Program; RENAC=National Network of Congenital Anomalies of Argentina; RYVEMCE= Mexican Registry and Epidemiological Surveillance of Congenital Malformations; TROCA=Tabriz Registry of Congenital Anomalies; SMC=Soroka Medical Center; UK=United Kingdom; USA=United States of America

Supplementary Table 3. Case counts and distribution of omphalocele cases according to clinical presentation by pregnancy outcome among, 18 birth defect surveillance systems with available data, 2000-2012

	Isolated Omphalocele					MCA Omphalocele					Syndromic Omphalocele				
	Total cases		Pregnancy outcome			Total cases		Pregnancy outcome			Total cases		Pregnancy outcome		
	n	%	LB %	SB %	ETOP FA %	n	%	LB %	SB %	ETOPF A %	n	%	LB %	SB %	ETOPF A %
<i>Hospital-based registries</i>															
Argentina – RENAC ¹	50	44 %	86 %	14 %	-	59	52 %	86 %	14 %	-	4	4 %	75 %	25 %	-
Colombia – Bogotá ¹	31	58 %	94 %	6 %	-	18	34 %	94 %	6 %	-	4	8 %	100 %	0 %	-
Colombia – Cali ¹	2	67 %	100 %	0 %	-	0	0 %	0 %	0 %	-	1	33 %	100 %	0 %	-
South America – ECLAMC ¹	31	39 %	90 %	10 %	-	48	61 %	74 %	26 %	-	-	-	-	-	-
	2	2 %	2 %	2 %	-	2	2 %	2 %	2 %	-	-	-	-	-	-
Spain – ECEMC	30	34 %	30 %	0 %	70 %	28	32 %	18 %	0 %	82 %	30	34 %	0 %	3 %	97 %
Mexico – RYVEMCE ¹	32	55 %	91 %	9 %	-	11	19 %	100 %	0 %	-	15	26 %	60 %	40 %	-
Israel – SMC ²	11	73 %	100 %	-	-	4	27 %	100 %	-	-	-	-	-	-	-
Total	46	42 %	87 %	9 %	4 %	60	53 %	74 %	22 %	4 %	54	5 %	31 %	15 %	54 %
<i>Population-based registries</i>															
France – Paris	49	24 %	63 %	6 %	31 %	42	21 %	29 %	5 %	67 %	11	55 %	7 %	3 %	90 %
Germany - Saxony Anhalt	32	46 %	50 %	9 %	41 %	21	30 %	10 %	19 %	71 %	17	24 %	24 %	0 %	76 %
Italy - Lombardy	5	21 %	60 %	0 %	40 %	12	50 %	50 %	8 %	42 %	7	29 %	14 %	14 %	71 %
Italy - Tuscany	37	49 %	46 %	3 %	51 %	20	26 %	15 %	5 %	80 %	19	25 %	21 %	0 %	79 %
Malta – MCAR ¹	3	21 %	100 %	0 %	-	8	57 %	88 %	13 %	-	3	21 %	67 %	33 %	-
Netherlands - North	19	32 %	84 %	0 %	16 %	8	14 %	88 %	13 %	0 %	32	54 %	19 %	9 %	72 %
Slovak Republic	30	55 %	90 %	0 %	10 %	22	40 %	95 %	5 %	0 %	3	5 %	100 %	0 %	0 %
Sweden	12	35 %	58 %	2 %	40 %	13	37 %	42 %	2 %	56 %	10	28 %	19 %	3 %	78 %
	6	6 %	6 %	6 %	6 %	5	5 %	5 %	5 %	5 %	0	0 %	0 %	0 %	0 %
UK - Wales	42	23 %	64 %	0 %	36 %	58	32 %	36 %	3 %	60 %	79	44 %	30 %	6 %	63 %
Ukraine - OMNI-Net	67	49 %	42 %	1 %	54 %	58	43 %	24 %	12 %	55 %	11	8 %	55 %	9 %	36 %
USA - Utah	61	31 %	77 %	10 %	13 %	55	28 %	71 %	15 %	15 %	83	42 %	48 %	17 %	35 %
Total³	47	34 %	61 %	3 %	35 %	43	32 %	43 %	7 %	49 %	46	34 %	25 %	7 %	68 %
All registries³	93	37 %	74 %	6 %	20 %	10	42 %	61 %	16 %	23 %	51	21 %	26 %	7 %	67 %
	9	9 %	9 %	9 %	9 %	41	41 %	41 %	41 %	41 %	9	9 %	9 %	9 %	9 %

MCA= multiple congenital anomalies; syndromic omphalocele =omphalocele with chromosomal or other genetic abnormalities; LB=livebirths; SB=stillbirths; ETOPFA=termination of pregnancy for fetal anomalies; ¹ETOPFA not allowed during (part of) surveillance period; ² data on live born children with congenital omphalocele from one hospital
ECEMC= Spanish Collaborative Study of Congenital Malformations; ECLAMC=Latin American Collaborative Study of Congenital Malformations; GP=General Practitioner; MCAR=Malta Congenital Anomalies Registry; OMNI-Net=Ukraine Birth Defects Prevention Program; RENAC=National Network of Congenital Anomalies of Argentina; RYVEMCE= Mexican Registry and Epidemiological Surveillance of Congenital Malformations; TROCA=Tabriz Registry of Congenital Anomalies; SMC=Soroka Medical Center; UK=United Kingdom; USA=United States of America

Supplementary Table 4. Mortality in live births affected with omphalocele by clinical presentation and registry type, among 19 birth defects surveillance systems with available data, 2000-2012

Country - registry	Isolated Omphalocele				Multiple Congenital Anomalies and Omphalocele				Syndromic Omphalocele			
	Number of Livebirths	0-6 days	7-364 days	5-Year	Number of Livebirths	0-6 days	7-364 days	5-Year	Number of Livebirths	0-6 days	7-364 days	5-Year
Hospital-Based Registries												
Argentina – RENAC ¹	43	23.3%	-	23.3%	51	60.8%	-	60.8%	3	33.3%	-	33.3%
Colombia – Bogotá ¹	29	10.3%	-	10.3%	17	35.3%	-	35.3%	4	25.0%	-	25.0%
Colombia – Cali ¹	2	0.0%	-	0.0%	-	-	-	-	1	0.0%	0.0%	0.0%
South America – ECLAMC ¹	282	16.0%	7.5% ⁴	23.4%	357	43.1%	12.6% ⁴	55.7%	-	-	-	-
Spain - ECEMC	9	0.0%	-	0.0%	5	20.0%	-	20.0%	-	-	-	-
Mexico – RYVEMCE ¹	29	13.8%	-	13.8%	11	18.2%	-	18.2%	9	55.5%	-	55.5%
Israel – SMC ²	11	0.0%	0.0%	0.0%	4	0.0%	0.0%	0.0%	-	-	-	-
Total	405	16.3%	23.7%	23.7%	445	44.3%	56.7%	56.7%	17	46.4%	46.4%	46.4%
Population-Based Registries												
Czech Republic	-	-	-	-	-	-	-	-	14	28.6%	35.7%	78.6%
France - Paris	31	0.0%	-	0.0%	12	8.3%	0.0%	8.3%	8	37.5%	0.0%	37.5%
Germany - Saxony Anhalt	16	0.0%	6.3%	6.3%	2	0.0%	0.0%	0.0%	4	0.0%	0.0%	0.0%
Italy - Lombardy	3	0.0%	33.3%	33.3%	6	0.0%	0.0%	0.0%	1	0.0%	0.0%	0.0%
Italy - Tuscany	17	5.9%	0.0%	5.9%	3	33.3%	33.3%	66.7%	4	50.0%	25.0%	75.0%
Malta – MCAR ¹	3	33.3%	0.0%	33.3%	7	14.3%	28.6%	42.9%	2	0.0%	100.0%	100.0%
Netherlands - North	16	0.0%	6.3%	6.3%	7	14.3%	28.6%	42.9%	6	66.7%	0.0%	66.7%
Slovak Republic	27	3.7%	0.0%	3.7%	21	23.8%	4.8%	28.6%	3	33.3%	0.0%	33.3%
Sweden	73	1.4%	4.1%	5.5%	57	3.5%	7.1%	14.0%	19	42.1%	31.6%	73.7%
UK - Wales	27	7.4%	7.4%	18.5%	21	33.3%	4.8%	38.1%	24	12.5%	16.7%	29.2%
Ukraine - OMNI-Net	28	0.0%	7.1%	7.1%	14	28.5%	7.1%	35.7%	6	33.3%	16.7%	50.0%
USA - Utah	47	8.5%	4.3%	12.8%	39	23.1%	12.8%	38.5%	40	35.0%	17.5%	52.5%
Total	288	3.4%	8.4%	8.9%	189	17.5%	27.1%	28.5%	131	31.6%	50.2%	54.7%
All registries	693	10.7%	16.7%	17.2%	634	36.2%	47.3%	48.3%	148	31.9%	52.2%	55.8%

¹ETOPFA (elective termination of pregnancies for fetal anomalies) not allowed during (part of) surveillance period

² data on live born children with congenital omphalocele from one hospital

³ total and cumulative percent mortality were calculated using a modified Kaplan-Meier Product-Limit method to account for censoring

⁴ incomplete follow-up, but deaths reported

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