

# PUBLIC SUBMISSION

**As of:** 5/8/23, 1:58 PM  
**Received:** February 20, 2023  
**Status:** Posted  
**Posted:** February 21, 2023  
**Tracking No.** led-qdxe-mdyl  
**Comments Due:** February 20, 2023  
**Submission Type:** Web

**Docket:** CDC-2022-0140  
Environmental Public Health Tracking Network

**Comment On:** CDC-2022-0140-0001  
Environmental Public Health Tracking Network 2022-27507

**Document:** CDC-2022-0140-0002  
Comment from Mazzella Jr., Silvio

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## General Comment

Docket CDC-2022-0140  
Document ID CDC-2022-0140-0001  
Environmental Public Health Tracking Network 2022-27507  
metadata included "( 1 ) birth defects prevalence"

### ESTIMATED ANNUALIZED BURDEN HOURS

Birth Defects Prevalence Form ... 30 respondents ...1,200 Total burden (in hours)

Opinion. ~ only 30? thus, only 1,200 hours?

How does this compare with other databases? the sum of fifty states, includes NYS DOH?

Example. "Table 1 Description of MTHFR gene-related entries

in current databases"

Leclerc D, Sibani S, Rozen R.

Molecular Biology of ... (MTHFR) and Overview of Mutations/Polymorphisms,

In: Madame Curie Bioscience Database [Internet].

Austin (TX): Landes Bioscience; 2000-2013.

Available from: <https://www.ncbi.nlm.nih.gov/books/NBK6561/>

The C677T mutation

of the ... gene is a moderate risk factor

for spina bifida in Italy. ... [ PMID : 26956130 ]

Geographical and ethnic variation of the 677C>T allele

of ... (MTHFR): findings from over 7000 newborns

from 16 areas world wide.

B Wilcken, F Bamforth, Z Li, H Zhu, A Ritvanen, et al. ( 2003 )

J Med Genet 2003;40:619–625

Data & Statistics on Birth Defects

Tetralogy of Fallot, Cleft lip with/wo cleft palate, ...

SB 1 in every 2.758 births

( Last Reviewed: December 21, 2022 )

[ <https://www.cdc.gov/ncbddd/birthdefects/data.html> ]

NYS DOH. Welcome to the Birth Defect Registry.

Revised: February 2022

( accessed February 20, 2023 )

[ [https://www.health.ny.gov/diseases/congenital\\_malformations/](https://www.health.ny.gov/diseases/congenital_malformations/) ]

New York State Department of Health

Birth Defects Registry

ICD-10 Coding Manual

List of all Reportable Congenital Malformations

[ [https://www.health.ny.gov/diseases/congenital\\_malformations/docs/bdrhandbook\\_v2.pdf](https://www.health.ny.gov/diseases/congenital_malformations/docs/bdrhandbook_v2.pdf) ]

The NY DOH Birth Defects Registry list includes these diagnosis codes:

1.741.0x

"Q05 Spina bifida (SB) Includes:

hydromeningocele (spinal), meningocele (spinal), meningomyelocele, myelocele,

myelomeningocele, rachischisis, spina bifida (aperta)(cystica), syringomyelocele

Excludes 1: Arnold-Chiari syndrome, type II (Q07.0-), spina bifida occulta (Q76.0)"

[ PMID : 10833329; 11509014; DHR, 17336564 ]

## 2. Neural tube defect 742.9

"Polymorphisms in folate metabolism genes as maternal risk factor for neural tube defects: an updated meta-analysis". ...  
[ PMID : 25005003 ]

" ... there is increasing evidence that many NTD  
are FA non-responsive. The vitamin-like molecule inositol  
may offer a novel approach  
to preventing FA-non-responsive NTD. ..."  
Inositol for the prevention of neural tube defects:  
a pilot randomised controlled trial. ... [ PMID : 26847388 ]

Inositol, neural tube closure  
and the prevention of neural tube defects. ...  
[ PMID : 27324558 ]

## "Q07.9

Congenital malformation of nervous system, unspecified  
Central nervous system (CNS) malformation, fetal  
Congenital anomaly NOS of nervous system  
Congenital deformity NOS of nervous system  
Congenital disease or lesion NOS of nervous system  
Nervous system anomaly"

## 3. Tetralogy of Fallot, "Q21.3

Tetralogy of Fallot (ventricular septal defect with pulmonary stenosis or atresia,  
dextroposition of aorta and hypertrophy of right ventricle) (also specify all individual defects)  
Dextraposition of aorta in Fallot's tetralogy ...". 745.2

## 4. Congenital Malformations of the Cleft Lip and Cleft Palate (Q35-Q37).

## 5. Congenital Malformations of the Urinary System (Q60-Q64)

Secondly, statistical accommodation(s) might have to be made  
for Autism ( Autism Spectrum Disorders ) research.

Example,

Association of methylenetetrahydrofolate reductase  
(MTHFR) gene C677T polymorphism  
with autism: evidence of genetic susceptibility. ...  
[ PMID : 26956130 ]  
[ <https://pubmed.ncbi.nlm.nih.gov/26956130/> ]

[ Metabolic biomarkers of increased oxidative stress  
and impaired methylation capacity in children with autism. ...  
[ PMID : 15585776 ].  
[ <https://pubmed.ncbi.nlm.nih.gov/15585776/> ]

PMID : 31200713; 33743119; 29578363; 34442354; 36112150; 34834493; 32892962; 34440744; 27755291;

<https://pubmed.ncbi.nlm.nih.gov/?term=31200713%3B+33743119%3B+29578363%3B+34442354%3B+36112150%3B+34834493%3B+32892962%3B+34440744%3B+27755291%3B>

Third, statistical accommodation(s) might also include  
the Healthy People 2030 objectives,  
among them, "dark green vegetables" of NWS-08

Healthy People 2030  
"About the Objectives"  
[ <https://health.gov/healthypeople/objectives-and-data/about-objectives> ]

"Increase consumption of dark green vegetables,  
red and orange vegetables, and beans and peas  
by people aged 2 years and over — NWS-08."  
[ <https://health.gov/healthypeople/objectives-and-data/browse-objectives/nutrition-and-healthy-eating/increase-consumption-dark-green-vegetables-red-and-orange-vegetables-and-beans-and-peas-people-aged-2-years-and-over-nws-08> ]

\*How about the VAERS ( as needed )?  
Thank You for considering my ideas.  
My reasons may change, as needed, of course.

Silvio Mazzella Jr.  
and the CDC & HHS Birth Defects Prevalence Form, NYS DOH BDR. folic acid & MTHFR. NTD. Autism. HP2030

( disclaimer ). IMO.GEM.NTH.SLP.