Evaluation of congenital malformations surveillance system in Albania during 2015

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Abstract

Aim: In Albania, since 2009, the Institute of Public Health (IPH) has established the Congenital Malformations Surveillance System (CMSS). No systematic evaluation for CMSS has been conducted and published before. Our aim was to evaluate CMSS in Albania during 2015 in order to better detect and prevent congenital malformations (CMs).
Methods: The evaluation process followed the Centers for Disease Control and Prevention guidelines for evaluating public health surveillance systems. The evaluation is focused on CMs reported in 2015, the latest year for which data set is available.
Results: The CMSS has a well-defined structure and is able to provide timely data. In general, CMSS is fulfilling its objectives by collecting, organizing, and distributing information on an important public health issue. Some of the major strengths of CMSS are mandatory reporting, low cost for coverage of a large population, flexibility to respond to changing conditions and resources, the narrative diagnosis for a better specificity (although it is not assessed in this evaluation report), and ongoing efforts to improve completeness of case ascertainment. Weaknesses include the lack of reported CMs among stillbirths and induced abortions, lack of an ongoing system for evaluating the accuracy of reported diagnoses, timeliness, and lack of completeness of risk factors data in the reporting form.
Conclusions: The CMSS is rather simple, accurate, stable, and flexible and provides valid data used at local and national level. But there is need to improve reporting of risk factors among all cases through a specific law or regulation in collaboration with different stakeholders, and to report CMs among stillbirths and induced abortions.

Keywords: congenital malformations, evaluation, surveillance.

Introduction

Congenital malformations (CMs) represent a significant health problem worldwide. The prevalence of specific CMs is different in different populations and its assessment depends on the health care system, the use and coverage of preventive services, access to screening, diagnosis and termination of pregnancy in severe cases (1-3). The prevalence of CMs varies from 10-60 per 1000 live births and this figure increases significantly if the CMs detected later in life (one year old to 5 years old) are included. CMs can be isolated abnormalities or part of a syndrome and continue to be an important cause of morbidity and neonatal and infant mortality (4). Different large population-based studies, report the prevalence of major malformations about 2-3% of all live births; between stillbirths prevalence of major CMs is even higher (5-9). Birth defects – or, according to the World Health Organization’s (WHO) term: congenital malformations – are structural, functional and/or biochemical-molecular defects present at birth whether detected at that time or not. Prior to 2009, limited diagnostic skills, poor health statistics, lack of Surveillance and of National Registry of Congenital Malformations and relying only in hospital records and not in population based studies, contributed to a situation of systematic underestimated prevalence rates of CMs in Albania. Consequently was born the necessity of establishing National Congenital Malformations Surveillance System (10). Until 2009, there was no other information with regard to major or minor CMs of genetic or partly genetic origin (10-12). Based on the International Classification of Diseases version 9 (ICD-9), doctors and/or nurses who follow up and assist in babies’ delivery in all maternity hospitals of Albania are obliged to record all CMs present in babies born alive and those who are born dead, according to the law No. 7687, date 16.03.1993. In March 2009 was drawn an order of the Ministry of Health (date 05. 03. 2009, Nr. 157) on the mandatory reporting of CMs identified during pregnancy, abortion, birth, stillbirth and until the age of 2 years old; for the public and private sectors of Albania (10). Public and private reporting centers sectors in our country are all maternity hospitals, general hospitals (who provide pediatric services), primary care (consultation of children services) and clinics or private hospitals that provide pediatric and obstetric-gynecological services, licensed by the Ministry of Health. Every diagnosed congenital malformation should be reported by an official individual form. Evaluation of CMSS is a systematic collection of information about this program that enables stakeholders to better understand the program, improve its effectiveness and/or make decisions about future efforts. Evaluation will help to understand where the program is working as intended, and the areas in need of improvement. The evaluation will help us to determine the information needs, for what purposes and how often. We evaluate the surveillance of congenital malformations in Albania using the Center for Disease Control and Prevention (CDC) guidelines for evaluating public health surveillance systems. In addition to the evaluation we assess the public health significance and usefulness of the surveillance system and how well it is meeting its objectives. The purpose of this evaluation is to assess the performance of CMSS as a surveillance system for detecting congenital malformations and preventing CMs through collaboration with different stakeholders (13,14).

Methods

Stakeholders are those persons and organizations, who provide and use data of CMSS, and they are as follows: public health specialist in the districts, health care providers (obstetrician-gynecologist, neonatologist and pediatricians), Ministry of Health, WHO office in Albania, UNFPA office in Albania, UNICEF office in Albania, private nonprofit organizations and representatives of affected communities with congenital malformations in Albania. The CMSS has been working to meet its stated objectives while struggling to improve its qualitative and quantitative attributes. Because it is a nationwide population based surveillance system, by now the strongest quantitative attribute is representativeness. The sensitivity of CMSS is difficult to evaluate, but available estimates suggests that CMSS identifies a large number of babies born with congenital malformations in Albania diagnosed at birth. The total number of CMs is reported officially by each district to the Ministry of Health, but the reporting form for each diagnosed malformation is reported to the surveillance system in IPH. We compare the data of reported CMs in the Ministry of Health with the data reported to the CMSS by district, and in each year since the implementation of CMSS, surveillance captures more cases (11,12). In the recent years, CMSS has been able to publish and disseminate annual reports describing the distribution of specific congenital malformations in Albania. CMSS can provide useful information to Maternal and Child Health programs. CMSS can help track the nation’s progress toward the Healthy People 2020 health promotion and disease prevention goals. CMSS can offer improvements over vital records when studying infant mortality in children with CMs. CMSS is population based and provides for descriptive and etiologic studies of birth defects. The utilization of CMSS data is going to be important for a number of stakeholders: public health experts, health professionals, policy makers and the public in order to meet its objectives and inform the population about various aspects of CMs in our country (10).

Therefore the use of CMSS information can be grouped into some main categories (15-17):

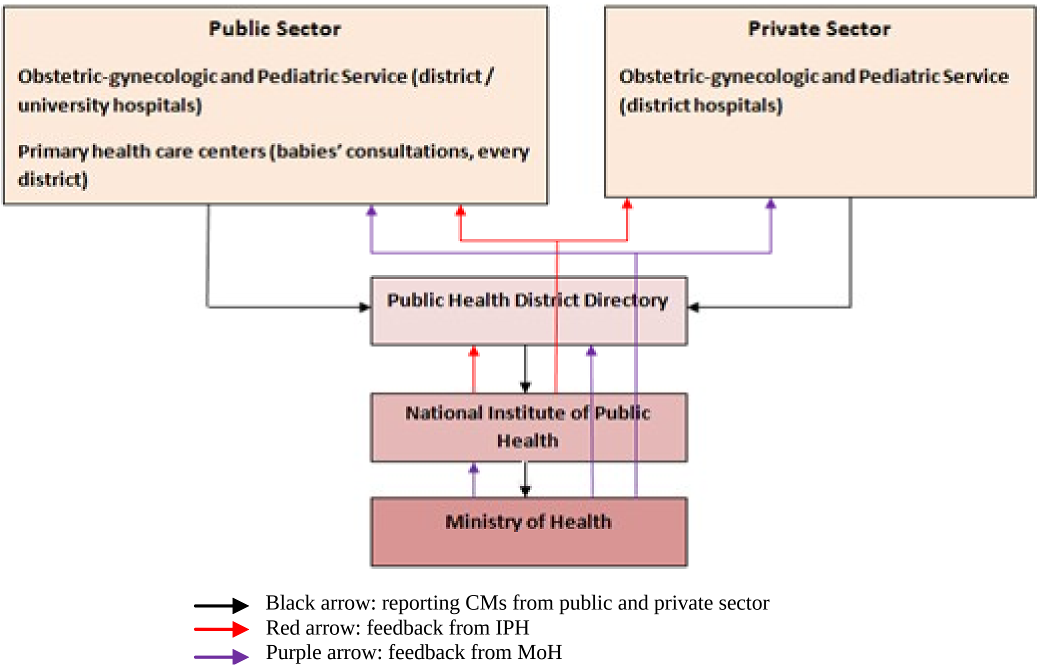
- Epidemiologic studies (detect diseases, trends);
- Mortality assessment;
- Needs assessment for services;
- Referral to clinics and services;
- Program evaluation (prevention and control of antenatal programs);
- Clinical research (improve clinical, behavioral, social practices).

System attributes

Simplicity

CMSS is a simple operating surveillance. The reporting form has the sufficient amount and type of data necessary to establish that CM has occurred, so the case definition is met. Information about demographic, exposure and health related events are obtained from the reporting form. A substantial number of reporters (physicians) from public and private health sector are included in the surveillance system. The reporting form is filled out by physicians (obstetric-gynecologist, neonatologists, and pediatricians). Diagnosis is written by physicians and coding according ICD9 is done in the IPH. Case reports (forms) are received by public health district directory (PHDD) and IPH. Public health specialist at PHDD collects every month the CMs forms from hospitals (maternity and general) of the districts and sends them every month to IPH. Also, every month PH specialist in the district controls if the all the fields of the CMs form are fulfilled, and if the number of completed forms matches with the number of the registered CMs in these institutions. Hence, this way, the CMs cases are easy to ascertain. Ten districts report CMs form electronically by the software and the original form via mail, and 26 districts report the original forms by mail. The software works only for data entry and it is easy for the RHI to make data entry and send them by email. IPH is the final institution which collects all the forms (electronically or hard copy), stores them, analyses and prepares the annual report for the Ministry of Health and sends feed back to each PHDD. Data are analyzed in SPSS software. The forms are saved as excel files and exported to SPSS for analysis purposes. There is always need for training the PH specialist of PHDD, and physicians regarding reporting CMs. IPH specialists monitor and train PH specialists and physicians of some districts every year. IPH is notified immediately as soon as a case of microcephaly or other malformations of nervous system are diagnosed. In this case, CMSS unit notifies the Department of Epidemiology of Non-Infectious Diseases and then both departments follow up the case for identifying the causes.

Figure 1. The flow of congenital malformation data



Flexibility

CMSS can accommodate to new CMs diagnosis, changes in the case definition or technology. CMSS does not need special funding for operating. Monitoring of the system in the districts is done within the existing human the financial resources of IPH and PHDD. The CMSS provides increased flexibility for database revision and data management and relay more immediate feedback to the districts. The data reported electronically are easily exported to excel and can be easily integrated with other systems. The reporting form doesn't allow adding questions or editing them, but in each section of the form there is the option "other" in order to add new information. The CMSS team has regular communication with public health specialist in the districts regarding the situation of CMs in the district and the challenges and problems within this district.

Data quality

Data quality of CMs reported forms reflect the completeness and validity of the data recorded in the CMSS (13,14). By examining the percentage of "unknown" or "blank" responses to fields of the form will be the best and easy measure of data quality. The information reported in the form is verified by the PH specialist with the case's information of the clinical file. If some of the fields of the form are blank, PH specialist should return the form back to the hospital (physicians) for collecting the information needed. There is still need for improving data quality of CMSS in Albania, because some of the fields of the reported forms are blank. The CMs form has more detailed information about socio-demographic characteristics and some risk factors of the case than the clinical file (standard format of hospital) does.

Table 1. Completeness of reporting of different fields in CMs form for the year 2015

Variable No.	Variables in CMs reporting form	Percent of completeness
I	**Information about health institution**	100
II	**General information for mother and father of the case**	
1	ID	100
2	Name/last name	100
3	Birth date	100
4	Birth place	100
5	Place of residence	100
6	Urban / rural	100
7	Ethnicity	100
8	Nationality	100
9	Education	100
10	Employment status and profession	100
III	**Information on previous pregnancies of mother**	
1	Previous pregnancies (born alive, fetal death, abortion)	70
2	Induced abortion because of CMs	60
3	Other children born with CMs	100
IV	**Obstetric-gynaecologic visits during current pregnancy**	
1	First visit	86
2	Second visit	84
3	Third visit	75
4	Fourth visit and other	88
V	**Information on baby with congenital malformation**	
1	ID	84
2	Date of birth	100
3	Gestation week	99.8
4	Gender	99
5	Place of delivery	100
6	Live status at birth	100
7	Measurements of the born baby	89
VI	**Information on risk factors for CMs in the current pregnancy**	
1	Conception way of fetus	0
2	X-ray radiation during pregnancy	0
3	Consumption of smoking, alcohol, illicit drugs by mother during pregnancy	0
4	Infectious diseases of mother during pregnancy	0
5	Non-infectious (chronic) diseases of mother during pregnancy	0
VII	**Medicaments eventually mother has taken during pregnancy**	
1	Medicaments by trimester	46
2	Folic acid during pregnancy	79
VIII	**Final diagnosis of CMs case**	
1	CM -I- suspected/confirmed	100
2	Date of diagnosis	100
3	CM -II- suspected/confirmed	100
4	Date of diagnosis	100
5	CM -III- suspected/confirmed	100
6	Date of diagnosis	100
7	Name/ last name of doctor (including signature and seal)	100

The main problem about reporting CMs is lack of reporting risk factors. During 2015 the percentage of reporting risk factors is 0 (zero). The main reported fields of the forms are those with socio-demographic characteristics. There is under reporting from some districts, especially the South and Central of Albania reports better than the North of Albania. The rate of reporting CMs for the year 2015 in Albania is 82%. We verify the number of reported CMs forms and the information of the form with the registered cases in the registries of the maternity hospitals and general hospitals. This matching process (monitoring and verification) is done by specialists of IPH once a year in some selected problematic districts, and every month by PH specialists of each district.

Acceptability

Acceptability reflects the willingness of physicians, Ph specialists, other specialists and health institutions to participate in the CMSS (13,14). In 2009 IPH was supported financially by UNFPA to build up the CMSS. UNFPA contributed till 2012, and up to now the system is managed and maintained by IPH. All physicians, RHI and PHDD were willing to collaborate, and more over that the reporting of CMs is mandatory by state regulations. All physicians acknowledge the public health importance of congenital malformations; nevertheless some of them neglect to fulfill the form or some parts (variables) of the form. Physicians see the completeness of CMs form as burdensome requiring additional time and staff (nurses or midwifes). PHDD is in charge of multiplying the CMs forms and supplying the hospitals of the district with these forms. The physicians are required to fulfill all the fields of the form and sign and seal the form. All physicians are trained on reporting CMs, but for about 5 years now no training was done regarding CMSS. There are 38 public health hospitals in Albania (providing pediatric and obstetric-gynecologic services) which are all included in the mandatory reporting of congenital malformations in Albania. Also, there are 2 main private hospitals (providing pediatric and obstetric-gynecologic services) in Tirana which are also included in the mandatory reporting of congenital malformations. In Albania there are 191 obstetric-gynecologist, 147 pediatricians and 55 neonatologists. They are all trained about the importance of congenital malformations and reporting of all diagnosed CMs in Albania. There are 36 public health specialists in the country (one per district), and they are all trained about reporting and monitoring CMs in their district. Case ascertainment in done by the public health specialist of the district, and in Tirana case ascertainment is done the public health specialists of the IPH working on CMSS. The overall reporting rate of CMs in Albania for the year 2015 is 82%. While we are facing some difficulties in reporting CMs in some districts, the reporting of CMs in Tirana is complete.

Representativeness

In order to be representative, CMSS must accurately describe the occurrence of congenital malformations over time and its distribution in the population by place and person. Representativeness is assessed by comparing the characteristics of reported CMs to all such actual CMs (13,14). The number of reported malformations to CMSS is higher than the total number of CMs reported officially to Ministry of Health from PHDD. But we still lack accurate information of CMs among terminated pregnancies, spontaneous abortions, stillbirths and up to the age 2 years old of the child, because CMs among live born babies are better reported then the other ones. The majority of CMs cases reported are among live born infants. The CMSS is a nationwide, population based registry that covers the whole population of births in Albania (30,000 births in 2015). Therefore, the results of epidemiologic studies using CMSS data (time, person place) can be generalized to the Albanian population at large. All the districts of Albania are covered with health facilities and medical staff providing pediatric and obstetric-gynecologic services. All births in the country occur in hospitals. All the public and private hospitals in Albania participate in reporting congenital malformations in the CMSS.

Timeliness

Timeliness reflects the speed between steps in the CMSS (13,14). The first interval is the amount of time between the onset of a CM, diagnosis of this malformation, reporting this malformation to PHDD and then reporting the case to the IPH, responsible for control and prevention measures. Factors affecting the time involved during this interval can include the pregnant mothers or child's requirement of medical care, the attending physician's diagnosis or submission of a laboratory test, the laboratory reporting test results back to the physician, the PH specialist collecting the forms from hospitals and then reporting to IPH (11,13,14). In general the diagnosis of CMs among live born infants is established within the first two weeks after the baby is born. This is the mean time of diagnosis calculated from the surveillance system (12). For each case the CMs form is fulfilled and at the end of the month PH specialist collects the forms from the hospital and sends them electronically or via mail to IPH within the first 10 days of the subsequent month. The second interval is the time required for the identification of trends, outbreaks, or the effect of control and prevention measures (13,14). Improving the completeness of case ascertainment, decreases timeliness. The matching process is largely responsible for the delay in the completion and dissemination of the annual report. The proper analysis and interpretation of CMs data require the calculation of rates. The denominators for these rate calculations are often obtained from a completely separate data system maintained by another institution such as Institute of Statistics and the Ministry of Health. The annual report for the year 2015 is completed during the second trimester of 2016 (11,12).

Recommendations

In order to meet its first objectives: assessing the prevalence of CMs and monitoring malformations according to type and different socio-demographic characteristics, the CMSS has published annual reports since 2009. The reports present the occurrence of CMs among live births in a specific cohort. The reports present demographic characteristics of babies reported to the surveillance, number of malformations, age at diagnosis and distribution of malformations by geographic region. Recipients of the CMSS annual reports include Ministry of Health, Public Health District Directories, public and private hospitals, researchers, interested individuals and nonprofit organizations. These annual reports are intended as a source for primary, secondary and tertiary preventive health care, and for reducing the overall morbidity and mortality. The semiannual reports of CMSS tend to investigate increases in the prevalence of CMs. In general, CMSS is fulfilling its objectives by collecting, organizing, and distributing information on an important public health issue. Some of the major strengths of CMSS are mandatory reporting, low cost for coverage of a large population, flexibility to respond to changing conditions and resources, the narrative diagnosis for a better specificity (although it is not assessed in this evaluation report), and ongoing efforts to improve completeness of case ascertainment. Weaknesses include the lack of reported CMs among stillbirths and induced abortions, lack of an ongoing system for evaluating the accuracy of reported diagnoses, timeliness, and lack of completeness of risk factors data in the reporting form.

Based on this evaluation, the main recommendations are as follows:

- To improve reporting of risk factors among all cases through a specific law or regulation in collaboration with different stakeholders;
- To improve reporting of CMs among stillbirths and induced abortions;

- To conduct routine monitoring in order to ensure that the activities of the surveillance system maximize case ascertainment;
- To improve the software of CMSS in terms of data entry and data analyses;
- To implement the electronic reporting in all districts of Albania;
- To continuously train the staff in Public Health District Directories regarding the surveillance system;
- To continuously train the physicians about the importance of reporting CMs and about new guidelines regarding preventive measures.

Conflicts of interest: None declared.

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