Surveillance of Hepatitis B in Malta - A four year trend

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ABSTRACT: Surveillance systems include three fundamental elements of ongoing collection, analysis and feedback or dissemination of the data. A surveillance system for Hepatitis B was established in 1988 in order to improve prevention and control of transmission of this endemic disease. A disease register including data obtained mainly from notifications, laboratory reports and active case finding was established. This paper shows the findings from 1990 to 1993. The system shown cannot claim to be complete. However the findings suggest that some 14 clinically evident cases of Hepatitis B are confirmed each year. No rising trend has been seen. In any one year a prevalence of 15.4 x 10^{-5} HBsAg positive results in persons who had previously not known that they were positive may be detected. Six month follow-up of these persons reveals that some 39 persons become chronic carriers each year. This has implications both for the targeted vaccination programme as well as for the individual's chronic liver complications and treatment.

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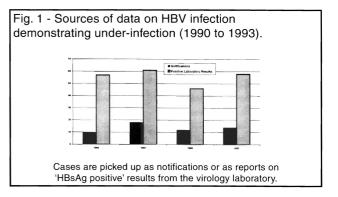
Introduction

The French word 'surveillance' was introduced into English at the time of the Napoleonic wars and meant keeping close watch over an individual or group of individuals in order to detect any subversive tendencies. Assuming that disease is undesirable, if not subversive, this sinister overtone is appropriate for the association of the word surveillance to disease. Indeed the term 'police medicine' was applied to the form of public health surveillance, evolved by Johann Frank in Germany in 1766 when he developed the concept of legal enforcement and a health care policy of legal enforcement¹.

The present concept of epidemiological surveillance emerged out of a system of rigid personal surveillance and sanitary control. The objective was to identify persons ill with a communicable disease, to isolate them and to take action to protect their entourage. In most countries this eventually led to a system of compulsory notification of communicable disease¹.

Those cases of hepatitis due to infection have been made notifiable through legal notices issued under the Prevention of Disease Ordinance and the Medical and Kindred Professions Ordinance, Chapter 31. However, this form of data collection is known to suffer from inconsistency, slowness of reporting, under-reporting and a heavy dependence on the personal initiative, motivation or individual enthusiasm of the notifying doctor (Figure 1).

The frequency of infection with hepatitis B virus (HBV) and its mode of transmission varies in different



parts of the world. In Northern America, Central and Western Europe as well as in Australia, the incidence of Hepatitis B is relatively low. In these areas, only 0.1%-0.5% of the population are hepatitis B surface antigen (HBsAg) carriers and these infections occur mainly in adults. In contrast in Asia, Africa and South America and the Pacific Islands, 5 to 15% of the residents are HBsAg carriers. The prevalence in Malta is thought to be similar to that of Western Europe though the carrier rate may be higher and is believed to be above 2%.

HBV infection is known to be a major cause of acute and chronic liver damage, liver cirrhosis and primary hepatocellular carcinoma². Moreover, one million Europeans are infected by Hepatitis B every year with estimates indicating that 90,000 will become chronic hepatitis carriers and 24,000 will die from the effects of chronic disease, cirrhosis and liver cancer³. This is six times the number reported in official statistics according to estimates by WHO⁴. As yet, hepatocellular carcinoma is not such a common occurrence in Malta, there being only about three cases per year⁵.

In Malta, hepatitis has become one of the most frequently notified infectious diseases in the 1990s (Table 1). Hepatitis (all types) was the 7th most

?	
Number of cases	Rank
679	1
n 106	2
77	3
48	4
33	5
21	6
lmonary 19	7
ıd	
19	7
e	
Number of cases	Rank
363	1
71	2
37	3
lmonary; 22	4
21	5
16	6
lary 15	7
	Number of cases 679 106 77 48 33 21 Imonary 19 id 19 e Number of cases 363 71 37 Imonary; 22 id 21 16

Table 1 - Reported new cases of selected notifiable infectious diseases 1990 and 1993

* Only 7 cases of Leishmaniasis in 1993, hence ranked below top seven rankings

** Rubella did not feature in top seven rankings in 1990 as there were only 14 cases

Source: Demographic Review of Maltese Islands, 1990 and 1993. Annual Reports 1990/93, Health Information Department

frequently notified infectious disease in 1990 and moved up to the 5th place in 1993⁶. An average of 22 new cases is notified annually. Of these, Hepatitis B is the most common - 60.67% (Table 2). This is known to be only a part of the true picture. Infections which are subacute or chronic (with no icteric course) are known to remain for the most part officially unreported² (Figure 1).

Method

All notifications of hepatitis B are referred to the Superintendant of Public Health where they are registered and referred to the Medical Officers of Public Health (MOH) for investigation. These are based at the Disease Surveillance Branch of the Public Health Department.

Another source of data is the medical diagnostic laboratories on the island, (in particular the Virology Department at St. Luke's Hospital). The laboratory based doctor is obliged by the Medical and Kindred Professions Ordinance (Chapter 31): "to give immediate notice to the Superintendent of Public Health any facts

Table 2 - Contribution of Hepatitis B to total
number of cases of Hepatitis notified

	Total no. of Hepatitis cases	Hepatitis A	Hepatitis B	Hepatitis NANB*
1990	19	6	10	3
	(5.27)	(1.68)	(2.80)	(0.84)
1991	22	3	18	1
	(6.11)	(0.83)	(5.0)	(0.27)
1992	27	14	12	1
	(7.43)	(3.85)	(3.30)	(0.27)
1993	21	2	14	5
	(5.73)	(0.54)	(3.82)	(1.36)
() = r	ate x 10 ⁻⁵			

*NANB = Non A Non B

Source: Demographic Review of Maltese Islands, 1990-93. Infectious Disease Notifications, Public Health Department

or circumstances touching the Public Health which may have come to his knowledge in the practice of his profession". This has always been interpreted as including any communicable disease laboratory results.

The drug abusers with acute hepatitis B undergoing long term rehabilitation at St. Mary's Hospital, Luqa, are reported and the doctors based there take on the responsibility of ensuring that all contacts are screened and offered immunisation. These patients are entered into this surveillance programme only when full notification is made by the hospital. Patients attending outpatient rehabilitation at the Detox centre, St. Luke's Hospital, on the other hand, are not entered into the surveillance programme because of confidentiality - no personal details being available.

The privately run Blood Bank at Floriana, which is complementary to the National Blood Transfusion Department at St. Luke's Hospital, notifies in confidence any patients who are detected by their screening programme. In 1993 alone, out of 4,276 donors only two (0.05%) were found to be Hepatitis B positive.

In the same year, out of 12,635 donations at the National Blood Transfusion Department, nine donors (0.071%) were picked up. Despite the small percentage involved, it is unfortunate that in 1991, this Department decided to stop referring their positive donors to the Public Health Department for follow up advice, counselling and preventive measures such as immunisation of close contacts. The Public Health Department is no longer informed of Hepatitis cases detected at the National Blood Transfusion Department and therefore such cases are not investigated or offered immunisation along the same lines described in this article.

After receiving the patient details, each MOH contacts the patient and with the help of a structured questionnaire, attempts to identify any risk factors or the possible source of infection. During this interview,

Department.

particular attention is given to the mode of transmission and to any potential direct (household) contacts. The MOH then, with the patient's consent, takes the opportunity to counsel the patient, his/her partner, and the remainder of the immediate family, answer any of their questions and educate them with regards to the precautions necessary to reduce the risk of transmission of the disease. A repeat HBsAg is taken to eliminate the possibility of a false positive result. Where indicated, HBeAg, anti-HBeAg, and anti-HBcAg may also be taken so as to obtain a clearer idea on the infectious/ immune state of the individual. The MOH will refer all contacts testing negative to the Floriana Health Centre for immunisation with 1 ml Engerix B and will follow them through the full course to prevent dropouts. Any contact testing positive is considered to be a new case in his/her own right and the procedure is reapplied to them and their own respective contacts. MOHs continue to offer their support, advice and other services to these persons should they be required. Once all this is done, the case is officially closed and the patient is advised to continue to go for regular clinical assessments at his GP or at the outpatients department if indicated.

The data generated from each questionnaire is captured on a Disease Register and entered on a DBase IV programme situated at the Disease Surveillance Branch of the Public Health Department. Personal details including name, address, telephone number, ID, date of birth are entered as well as other details such as occupation, past medical, surgical and social history or any history of travel. Other possible risk factors are also entered in the register including, sexual contacts/ preference, history of IV drug abuse, etc. The type and onset of clinical features is also important. The direct family contacts are listed together with their ages and relationship to the patient under investigation. Personal details of these contacts are taken to enable them to be traced again should this become necessary in the future. All laboratory results of blood taken from contacts, as well as the dates of vaccination are recorded. Needless to say, this information is regularly updated by the MOH and treated with absolute confidentiality at all times (passwords, locked discs).

All persons with HBsAg are recommended to have a repeat test done six months later. For the purposes of this disease register, a chronic carrier is defined as a person with two positive HBsAg results six months apart. The number of cases investigated over the four year period by the Public Health Department can be noted in Table 3 together with the resulting outcome of the investigations.

Results and Discussion

Assuming all notified cases to be symptomatic or icteric cases and all other unnotified laboratory reports to be asymptomatic (hence anicteric cases better referred to as subacute or chronic cases), Figure 1 shows the discrepancies between these two groups of patients. This is in keeping with reports from Northern Europe which suggest that there are an estimated three cases of anicteric Hepatitis B for every icteric case⁷.

The most commonly affected age is the 36-45 year group (Table 4). This differs from other published work in various parts of Europe which shows that in areas of low hepatitis B endemicity, the majority of infection

Table 3 - Outcome of Hepatitis B cases
investigated by the
Public Health Department

Year	Acute (Chronic	Lost	Deceased	Total
1990	5	46	5	1	57
1991	9	44	7	1	61
1992	5	31	7	3	46
1993	7	34	14	4	59
Source:	Hepat	itis B	Registe	er - Publi	c Health

occurs in people aged 15-34 years, rising in the late teens to a peak in the twenties and then tailing off^8 .

Also, HBsAg positivity is found twice as commonly in males than in females (Figure 2).

Table 4 - Age-sex distribution of HBsAg positive patients

Age group (yrs)	Males No.	Females No.	Total No.
0 - 15	4	11	15
	(0.88)	(2.55)	(1.70)
16 - 25	10	10	20
	(3.87)	(4.10)	(3.98)
26 - 35	32	14	46
	(11.23)	(5.13)	(8.25)
36 - 45	42	17	59
	(14.50)	(5.91)	(10.22)
46 - 55	22	11	33
	(11.4)	(5.32)	(8.26)
56 - 65	20	4	24
	(13.73)	(2.28)	(7.47)
66+	9	4	13
	(5.96)	(1.98)	(3.69)
Fotal	139	71	210
	(7.82)	(3.9)	(5.84)

Ratio: males to females 2:1

Taking end 1991 population as denominator (Demographic Review 1991)

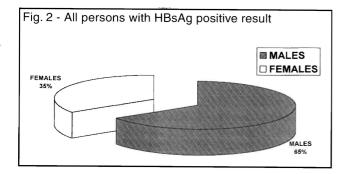
() = Age specific rate x 10^{-4}

Source: Hepatitis B Register - Public Health Department

Though the number of deaths in Hepatitis B patients as seen in Table 3 may seem to be significant, official statistics registered at the Health Information Department show that mortality from Hepatitis B as a primary cause is rare. Only one case was registered as having Hepatitis B as the primary cause of death (see Table 5).

Modes of transmission

The leading risk for transmission in developed countries is multiple partner sexual activity.



Unfortunately this is not an area where much research has been carried out in our population, though it is undoubtedly the more significant risk factor. We tried to determine probable modes of transmission from the data in the surveillance programme but the main difficulty was in validating the reliability of the data.

When looking at the intravenous drug users (IVDU), from all patients attending the Detoxification Centre at St. Luke's Hospital screened from 1987 to mid 1994, only 2.75% of the 800 attenders were Hepatitis B positive, which does not make this a predominant mode of transmission of the disease on the island so far⁹. Unpublished data on Hepatitis C gives a completely different picture. Approximately 60% of IVDU patients attending the health services are believed to be Hepatitis C positive¹⁰.

Newborn infants of highly infectious carrier mothers are also known to run a 70-90% risk of developing hepatitis B infection and up to 85-90% chance of becoming a chronic carrier¹¹. However a local study done in 1993 which looked at almost 1000 attenders at the Antenatal Clinic at Karen Grech Hospital showed that less than 1% were found to carry the hepatitis B marker¹².

Children are especially vulnerable and in infants the risk of infection per exposure is even greater, i.e. 10 - 15 times that of the general population. It has been shown that within households with two or more children infected with hepatitis B, it is likely that child-to-child transmission may also occur¹¹. This may in fact account for the transmission that is known to occur in institutions.

A US study showed that in families where the parents were not hepatitis B carriers but one of the children was, 25% of other children in that family had been infected with hepatitis B and these children with hepatitis B are more likely to become carriers of the virus than adults¹¹.

Universal vaccination of young adolescents is known to be difficult because it relies on administering three doses of vaccine to 10 - 12 year olds - a group in whom compliance is poor. Therefore, an easier alternative would be to introduce the vaccine in the routine childhood immunisation programme, as is being advocated by WHO.

Studies carried out by WHO in Italy show that a regular sexual partner of a Hepatitis B carrier has an 18 - 30% chance of infection while those living in the same house as an HBV carrier have the same likelihood of infection as sexual partners. In fact, household contacts can have up to three times greater risk of infection with Hepatitis B than the general population¹³.

Analysis of this surveillance data on Hepatitis B cases shows that positive secondary cases in household

Table 5 - Hepatitis mortality 1990-1993. Yearly mortality from Hepatitis B compared to non A non B (NANB) and AIDS.

Year	Нер В	NANBHep	AIDS	
1990	0	0	2	
1991	0	0	3	
1992	1	0	5	
1993	0	2	2	

Source: Health Information Department

contacts of a case are not an uncommon occurrence. Possible routes of transmission in household contacts are thought to be through spots of the carrier's blood on the towels or other surfaces coming into contact with microlesions on someone else's skin. Nail-scissors and razor blades may also contribute, as well as the sharing of intimate objects like toothbrushes ¹¹.

It is important to trace and immunise all direct household contacts and to prevent chronic infection with Hepatitis B virus in Malta. This demands a strict immunisation programme for all contacts. A selective policy of vaccinating only the high risk groups against Hepatitis B is known to be the most rational prevention strategy but it has been shown in some cases to be inadequate and of limited success⁷. Only about two thirds of contacts accepted the vaccination, a situation which we would like to see improve (see Table 6).

The Health Division is currently reviewing the Hepatitis B immunisation policy and a national campaign was planned to be initiated some time in 1997,¹⁴ though details on how the programme will be run are still to be announced. WHO recommends that hepatitis B immunisation programmes should be considered in all population groups who have chronic carrier rates of hepatitis B virus of over 2%¹⁵. Moreover when a carriage rate reaches 3%, WHO recommends that the Hepatitis B immunisation programme should be introduced as an integral part of existing childhood immunisation programmes with the individual being vaccinated as early as possible⁸.

The main objective of any immunisation programme should be to prevent chronic carriage of Hepatitis B virus: "The evidence for an association between the

Table 6 - Number of direct contacts vaccinated

Year	Persons offered immunisation	Persons accepting immunisation	Percentage acceptance
1990	182	124	68.13%
1991	187	128	68.45%
1992	138	103	74.64%
1993	132	74	56.06%

Source: Hepatitis B. Registers - Public Health Department.

carrier state of hepatitis B virus infection and hepatocellular carcinoma (liver cell cancer) is now sufficiently strong to justify the use of a vaccine against this infection as a means of preventing this cancer.¹⁶"

When any country considers whether to embark on an immunisation programme using HB vaccine, it must determine what the level of risk in that country is before committing extensive resources. Collecting systematic health and disease information is important since this forms the basis for the description of the health dynamics of populations¹. Surveillance systems also help to set priorities concerning health improvements and to introduce effective measures including disease control and prevention, immunisation and education programmes.

Collation of data from different sources and from all over the country is fundamental since the success of any surveillance system depends greatly on the quality of data collected. Also quick, reliable and accurate analysis together with timely publication of results in an acceptable format is an α_i ea for future development to improve the system¹⁷.

Unfortunately, it is not possible to estimate the true incidence/prevalence in Malta, even with expensive special studies. The data in this registration system can never be complete although efforts to eliminate major gaps are finally working and improvements are being noticed.

The gaps in this data are mainly due to noncompliance to the Prevention of Disease Ordinance. It is therefore important that the responsibility for this system of notification and registration is accepted not only by the Government Departments involved, but also by the doctors who have a vital role to play through their obligation to notify.

Finally, the vaccination schedule to be adopted nationally should be planned not only according to the carriage rate estimated by this and other studies, but also according to the delivery capacity of the health system in terms of human and financial resources¹⁵. Perinatal transmission and death rate from liver disease attributable to chronic HBV infection do not seem to be decisive factors in the local context.

Conclusion

The data analysed in this surveillance programme is insufficient and has gaps that are dependant on a variety of sources. Whilst non-compliance to the law is a major factor, other problems such as "ownership" of data with reluctance in forwarding information from one branch to another is also an issue. Accurate prevalence and incidence studies are desirable, but these require expensive studies which would still only provide an estimate of the true picture.

Despite the above deficiencies, this surveillance system shows that hepatitis is one of the most prevalent notifiable infectious diseases in Malta with 20-25 infections annually. 60.67% of these are Hepatitis B with 14 new clinical cases confirmed annually and 39 persons becoming chronic carries. It is twice as common in males and is believed to be mainly transmitted through household contact and unprotected sex. A programme of immunisation for household contacts already exists and runs smoothly through the Floriana Immunisation Centre. At present, an immunisation programme targeting 10-11 year olds is being planned to be launched in the immediate future. However this strategy should be revised and a national campaign of vaccination starting with childhood immunisation programmes should be considered.

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