



**Article title:** The Neonatal Hearing Screening Program in the Maltese Islands: Shining a spotlight on a national pilot project

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**The Neonatal Hearing Screening Program  
in the Maltese Islands:  
shining a spotlight on a national pilot project**

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***Abstract:***

An established neonatal hearing screening program is a direct indicator of the health and security index of a country. Its importance has been emphasised by WHO since 1995 and is now an anticipated standard of care in the developed world. The aim is for this standard to become a globally unquestionable prerequisite for healthcare. This study casts a detailed look at the neonatal hearing screening pilot project within the Maltese Islands, which was thereafter planned to be implemented on a national level to safeguard the future generation, make available timely responses and put the nation on the global map of a high standard of healthcare. This pilot project studies the outcomes of the collected data. From a sample of 1877 neonates born between October 2020 and September 2021, it was found that the rate of incidence of neonatal hearing loss identified at screening was that of 5 neonates, equating to 0.3%. This was a statistic comparable to various other studies done in different countries. It is notable that whilst it is known that NICU neonates are at an increased risk of hearing loss, none of the affected neonates in the pilot project were from this subgroup of recruits. In conclusion, the pilot project produced good results and gained satisfactory departmental feedback. An established national screening program is now in operation.

***Keywords:***

Neonatal, Hearing Loss, AABR, OAE, data, health.

***Acronyms:***

AABR: automated auditory brain response

OAE: otoacoustic emissions

NICU: neonatal intensive care unit

WHO: World Health Organization

## ***Introduction:***

Care of the neonatal population has always had a particular level of importance in our societies. It is possibly regarded with a sense of responsibility towards safeguarding a good future for the next generation. Undoubtedly, screening of the neonatal population for various possible pathologies has now become an expected practice worldwide and standardisation of programs are commonplace. The neonatal hearing screening program is one such practice that has become globally accepted to be one of the expected surveillance practices in the developed medical world.

Hearing loss is the 4<sup>th</sup> leading cause of disability worldwide, which is estimated to cost over 750 billion dollars every year. It was in May 1995 that the WHO first issued a working agenda for the prevention of hearing impairment, listing universal neonatal hearing screening as a recommendation to be implemented in all countries globally with provision of rehabilitation services (WHO, 2018). Repeat WHO circulars are regularly issued on the matter, highlighting both its importance as well as the presumable slow implementation of such measures.

Congenital hearing loss affects approximately 2 per 1000 births, with a higher prevalence in NICU neonates, the rate rising to 1 per 100 NICU admissions. Its early detection, investigation and intervention is vital for the functional and social prognosis of the child. A missed diagnosis of hearing loss can have a devastating impact on the speech, language and cognition of the child, which directly impact the child's emotional and social health (Oudesluys-Murphy, 1996; Busse, 2020). These children should be given the best chances at optimal development by means of early adjuncts in cases of confirmed hearing impairment. Currently, in the USA, over 45 states are legally obliged to screen at least 95% of the new-born population (NCSL, 2021).

Malta is a small island archipelago in central Mediterranean with a population of just over 440,000 and a birth rate of approximately 3000 neonates yearly. A formal neonatal hearing screening protocol was introduced as a pilot project in 2020, a notable 25 years after the first WHO neonatal hearing screening declaration (WHO, 2010). This study is the first of its kind within the Maltese Islands and is specifically aimed at identifying the incidence of neonatal congenital hearing loss in the Maltese population. A secondary objective was to conduct a literature review

with the intention to compare our results to the international picture and identify ourselves as to how we fare on the world map.

The neonatal hearing screening program process may vary slightly between different nations. However, the main concept is to identify the sound detection threshold by neonates. The threshold is normally between 20-40 dBnHL and both ears are to have their thresholds tested. The two mainstay tests in use are transient otoacoustic evoked potentials (TOAE) and automated auditory brain responses (AABR) (Kennedy & McCann, 2004). OAE is approximately 77% sensitive and 93% specific, whilst AABR is approximately 93% sensitive and 97% specific (Heidari, 2015). This implies that combined, these tests have an overall sensitivity and specificity of over 90%. Whilst both are non-invasive methods of testing, AABR is more laborious and neonates may tend to be less compliant. It is for this reason why locally OAE were the test of preference for non-NICU neonates, whilst a combination of AABR and OAE were the mainstay screening for NICU neonates.

### ***Method:***

This study is divided in two and was conducted within Mater Dei Hospital, which is the main regional public hospital and only teaching hospital of the Maltese Islands. The data collected also includes the neonates born at Gozo General Hospital, the hospital on the sister island to the mainland. The exclusions are the neonates born in private hospitals, which amount to the very minority of births. It also excludes a number of neonates born within Mater Dei Hospital, which for some reason or another, were missed from screening – these reasons shall be discussed later in this writeup. The included neonates were recruited on discharge of mother and baby from the obstetrics wards, or whilst the neonate was in NPICU. The selected timeline under study was agreed on to be a year, from when the pilot project study started, i.e., October 2020 to September 2021. In total, 1947 neonates were recruited and included in this study.

The data was collected and saved by the team of audiologists manning the audiology department at the said hospital. This was tabulated using a pre-set proforma which is described below. Neonatal screening has now become part of the daily job of the Maltese audiologist. For

the purpose of this pilot project, the neonates were screened whilst the mother was still an inpatient postpartum, but it is notable to mention that international standards guide that initial testing ought to be scheduled within the first 3 months of life and not necessarily right at birth.

The proforma used was tabulated in the following manner: (i) name and national identity number, anonymised for the purpose of this project; (ii) age at time of test, in hours or days. (iii) AABR Left; (iv) AABR Right; (v) OAE Left, if needed; (vi) OAE Right, if needed (vii) date and age of second test, if needed; (viii) AABR Left – second test; (ix) AABR Right – second test; (x) OAE Left – if needed, second test; (xi) OAE Right – if needed, second test; (xii) referral for Hearing Aid/BAHA/Cochlear Implant.

Data was recorded in per year (2020 and 2021) and per ward (NICU, Obstetrics wards – 3 in all). No distinction was made between Gozo and Malta screening, which are both the habited islands of the archipelago. Tabulation was conducted by hand i.e., data was physically written down on paper forms and thereafter these were scribed onto an electronic data sheet (Microsoft Excel).

Data to conduct this study was provided following approval of the local health authorities comprising of the hospital management, data protection approval, legal office approval and ethics board approval. In the first stage, retrospective data is collected of the test results of the neonates who underwent the pathway of neonatal hearing screening.

It is well known that some new-borns are more susceptible to hearing loss than others. Those specifically include preterm neonates and neonates born with particular difficulties necessitating NICU admission. Hence the results extrapolated from this methodology are subsectioned as follows: (i) NICU data; (ii) all other non-NICU data; (iii) cumulative data  
This is done for the purpose of identifying any differences in incidence of hearing loss between the two subsets, one of which is undoubtedly at a predetermined disadvantage.

At the initial appointment of neonatal audiological testing, the first test performed was an OAE on both ears, followed by an AABR if there was any doubt from the OAE or the OAE was not successful. The exception to this rule were the NICU neonates, who were all subjected to both an OAE as well as an AABR, even if the either was successful bilaterally.

A subsequent appointment was given only if the neonate failed the tests subjected during the first appointment.

For the second stage of the study, a brief literature review of the neonatal screening patterns and results in foreign countries was carried out – both for the sake of comparison of standards as well as incidence and prevalence of pathology within the Mediterranean community of the Maltese islands to similar and contrasting populations.

### ***Exclusions:***

Only the children born in public national hospitals were included in this study, meaning that the number of neonates born in private hospitals in Malta during the timespan of data collected were excluded. These amount to approximately 150 neonates in 1 year.

As a general rule, the neonates who could not attend their first appointment for whatever reason, were given another appointment within the shortest of time possible to ensure that they are tested. Lack of attendance for both birth and consecutive appointments led to the cases being excluded from the study.

Another exclusion were the few neonates who had much of the data recorded missing. These only accounted for less than 10 neonates; however, it is unsure why these data slots were not filled – it is possible that this is a simple case of human error, assumption or because the tests could not be conducted for whatever reason. A few minor subsequent exclusions are recorded in the results section and the data analysis taking them into account – the main concern being lack of human documentation.

### ***Results:***

From the collected data, it can be observed that there were a total of 1877 neonates (864 in 2020, 1017 in 2021), out of which 627 (413 in 2020, 214 in 2021) were NICU admissions. This



implies that out of the audited cases, 33.4% of neonates were at a non-questionable increased risk of hearing loss, dictated by being born with unfavourable conditions causing care within NICU.

It was noted that NICU admissions did not have the neonates' age tabulated for their initial test. Unfortunately, this was also not tabulated for a minority of non-NICU neonates. For the non-NICU audited neonates, the greatest majority of tests were conducted within the first 2 days of life.

Excluding the NICU neonates and the undocumented non-NICU neonates, as well as one particular case where the first appointment was carried out after 5 months secondary to social difficulties, the total documented ages were provided for 1140 non-NICU neonates. Note is made that the former statistic was extrapolated following 737 exclusions – deducting 627 NICU neonates and the previously specified 1 non-NICU neonate, this leaves us 109 neonates who did not have their age of testing documented.

Mean age of testing was that of 49.7 hours of age, whilst the median age was that of 42 hours of age.

Out of the total of 1877 tested neonates, 1505 neonates passed the screening tests whilst 373 needed retests. Out of these, 183 were NICU neonates and 190 were non-NICU neonates. This translates to having to retest 19.8% of all neonates. Overall retests were more commonly needed for NICU neonates rather than non-NICU neonates. Indeed, 15.2% of non-NICU neonates and 29.2% of NICU neonates needed retests.

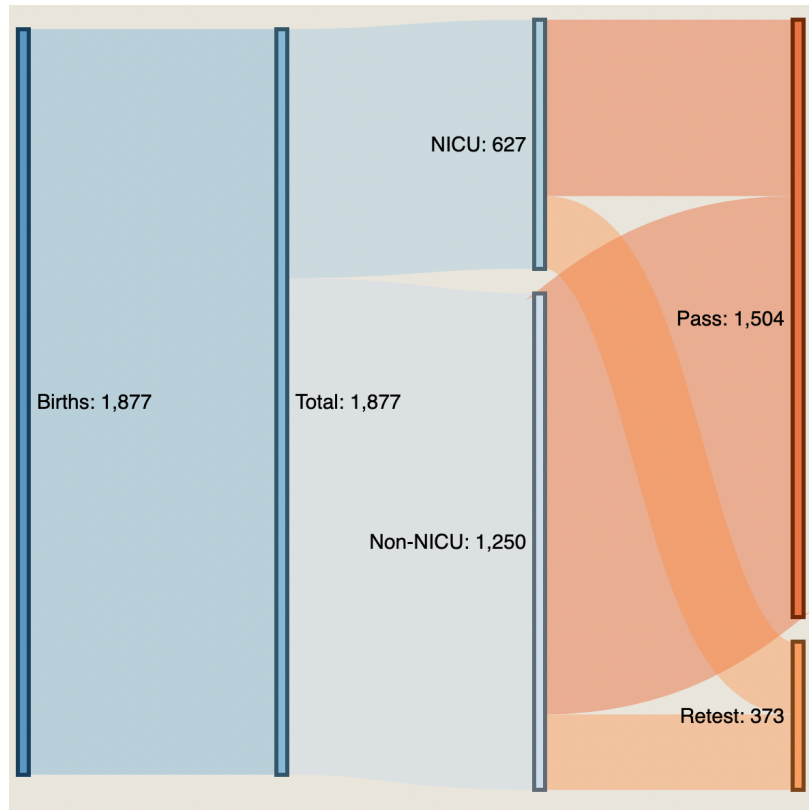


Figure 1. A demographic showing the pilot project outcome of NICU, non-NICU passes and retests.

Out of the 373 requested retests, it was noted that further data was not available for a total of 31 neonates, 5 of which were from NICU. Whilst 8 of these neonates were documented to have missed out on their retest due to parental refusal, and all 8 were non-NICU neonates, the rest had no date and no documented comments, implying that lack of data for these neonates was due to lack of documentation or human error. Whilst no comment can be made for the neonates with missing data, the fact that NICU-neonates' parents being more cooperative with follow-up is well documented in literature, in comparison to follow-up of neonates born with no apparent adversity.

Excluding these 8 neonates, of the 365 documented retested neonates, 7 neonates were thereafter referred to ENT specialists for further follow-up and consideration of treatment for what was ought to be confirmed hearing loss. The rest all passed their test on the second appointment.

Of these 7 investigated babies, 1 was eventually fitted with a BAHA and 2 were fitted with a cochlear implant. The remaining 4 were further evaluated and 2 were eventually fitted with hearing aids. All 7 babies remain under the close assessment of ENT and Paediatric specialists. It is interesting to note that none of the 5 babies needing hearing assistance were NICU neonates, despite this group being at an increased risk of hearing loss.

This implies that out of this pilot project of screened neonates, 5 out of 1877 neonates within the system were documented to have diagnosed hearing loss requiring intervention. This would account for 0.3% of births per pilot-project-year, which extrapolated to Malta's population (443,388 in December 2021) would statistically account to 1330 individuals suffering from some degree congenital hearing loss.

In the obtained data it was notable that whilst the NICU recruits were all subjected to both an AABR and also an OAE on both ears irrespective of either result, the non-NICU recruits were initially subjected to an AABR on both sides and an OAE conducted only if there was any need. This difference in screening between both groups of recruited neonates stems from the fact that NICU neonates are known to be at higher risk of hearing loss and that OAE have a relatively high false positive rate. Since an AABR has a lower false positive rate than an OAE, when coupled, the results are more reliable. However, an OAE is much less laborious and time-consuming to carry out on the neonate, leading to higher rate of co-operation by the neonate to complete the screening test. Hence it is for the sake of safety and for ensuring accurate results, that the somewhat disadvantaged NICU neonates were subjected to both tests in contrast to the non-NICU neonate group (Ngui, 2019).

By extrapolating the non-NICU data, out of 1250 neonates 150 neonates had to have an OAE following an AABR, which makes up 12% of non-NICU neonates causing some doubt and needing reassurance of results.

### ***Discussion:***

The recorded data was noted to be lacking a few demographic details which would have been interesting to record and evaluate. One such demographic which has not been added is gender of

the neonate undergoing the test. It would have been interesting to audit the gender difference, if any is present.

Another demographic of note is the mode of delivery of the neonate in question. It was observed that this was only recorded in approximately half of the neonates under study. Whilst the results extrapolated from the documented cases yield interesting results, it can also be argued here that were all the neonates to have this information recorded, would the outcome be significantly different.

It is well known that neonatal hearing loss may be syndromic. The collected data has no record of neonates who may have been born with a known syndrome. It would have been interesting to know if the neonates needing intervention, needed hearing intervention in isolation or not. This goes hand in hand with reporting of congenital conditions to the public health institutions, as such data pre-empts the needs of the young generations as they grow up, both in social terms as well as for financial budgeting and healthcare resources to be made available. Auditory rehabilitation, educational assistance, and the need for adjuncts such as hearing aids and cochlear implants are examples. The resources are not simply material but also manpower and expertise of professionals in the field.

Of the data collected, occasionally data entry slots were left empty, such as weeks of gestation or age at time of test. For this reason, on accounting for the variable in isolation, these omissions led to cases being excluded from the study. Whilst these were the very minority of cases, one cannot help but commenting that such a deviance leads to the possibility of questioning whether without these omissions the obtained results would vary in a significant way. It also causes the argument of reliability of the communicated data which is subject to human error. Avoidable human error could have been prevented by collecting data a technological proforma such as online Google Sheets, making sure no slots are to be skipped or left empty.

The degree of hearing loss is not accounted for in this study and was not part of the agreed documentation proforma. Thus, for the 5 neonates referred for professional review, the dB loss was not documented. The scope of neonatal hearing screening is not to provide diagnoses with accuracy but rather to pick up any significant aberration. Not all neonates who failed the test are

necessarily deaf but most likely have a mild/moderate degree of hearing loss. This implies that the future needs of these neonates are variable and does not necessarily fall under a uniform category. Also, of note would have been the international comparison of the degree of neonatal hearing loss.

It is relevant to note that this audit was carried out during a period of time where the world was experiencing the emergence of the novel Covid-19 pandemic. Being still under study, it would be interesting to investigate whether expectant mothers who were unfortunately affected by the viral illness gave birth to neonates who had some form of hearing difficulty, whether this was temporary (translating as initial failure of passing the test, followed by a pass at a later appointment) or permanent (persistent failure of test). It is not yet known what are the long-term effects on neonates of mothers contracting covid during gestation and it would be beneficial to know if there are developmental sequelae affecting these children.

Sequi-Canet and Brines-Solanes in their 2021 publication exploring the lessons learnt through 30 years of experience, argue that, despite the possibility of screening to be conducted by doctors, nurses and audiologists alike, the best identified professional to conduct or offer the most help is the obstetric nurse. This has the advantage of numerical manpower in comparison to other professions as well as the assurance that no mother is discharged from hospital without having had her child screened, especially when these discharges happen over weekends or holidays and other members of staff in other professions would not be available to screen, may it be due to lack of manpower or lack of available facilities secondary to closed clinics. The disadvantage of the obstetric nurse lies in the fact that the obligation to undergo audiological training to be able to do screening is an ethical dilemma. Between an already heavy workload and a career that is professionally trained to deal with much different healthcare aspects, adding on more work, moreover being far different than their particular focus, may be the cause of apprehension, anxiety or lack of motivation (Sequi-Canet & Brines-Solanes, 2021). It is indeed notable that the formerly mentioned exclusions to this pilot project remain mindful that neonates discharged on weekends and public holidays were missed from being recruited due to lack of staff working on these particular days.

It could be argued that the results obtained relating to the number of repeat assessments are an unnecessary source of anxiety since a proportion of them are a simple by-product of the difficulty in having a neonate which is fully cooperative to an AABR/OAE. It must be kept in mind that an AABR involves fitting probes in ears and placing electrodes on the head of the neonate, whilst an OAE also uses probes and generates startling sounds (Ngui, 2019). This handling might cause the neonates to be restless, cry. One needs to remind mindful that a distressed neonate may translate to a distressed parent, who may feel that his/her child is not being treated in the most gentle of ways. It is possible that some lack of cooperation for follow-up from parents may be due to this fact.

A brief literature review of published audits which were very similar to the one conducted for the purpose of this local study, shows that for similar cohorts, the prevalence of neonatal hearing loss seems to be rather uniform worldwide, with differences in between different continents being attributed to social and cultural differences (Kenna, 2003).

In a published study on neonatal hearing loss in Sicily showed that there is a prevalence of 1.5% (Ferlito, 2021). A prevalence of 1.6% was obtained in the Lazio Region in Italy (Turchetta, 2018), 1.3% in France (Doncarli, 2019), 0.9% in Sweden by (Uhlen, 2020), and an impressive 0.1% in Greece (Kosmidou, 2021). This was reported as 0.3% in Japan (Sato, 2020) as well as all of the UAE (Rehman, 2012), 0.4% in Iran (Sabbagh, 2021) and 1.3% in Sharjah by (Ayas, 2021).

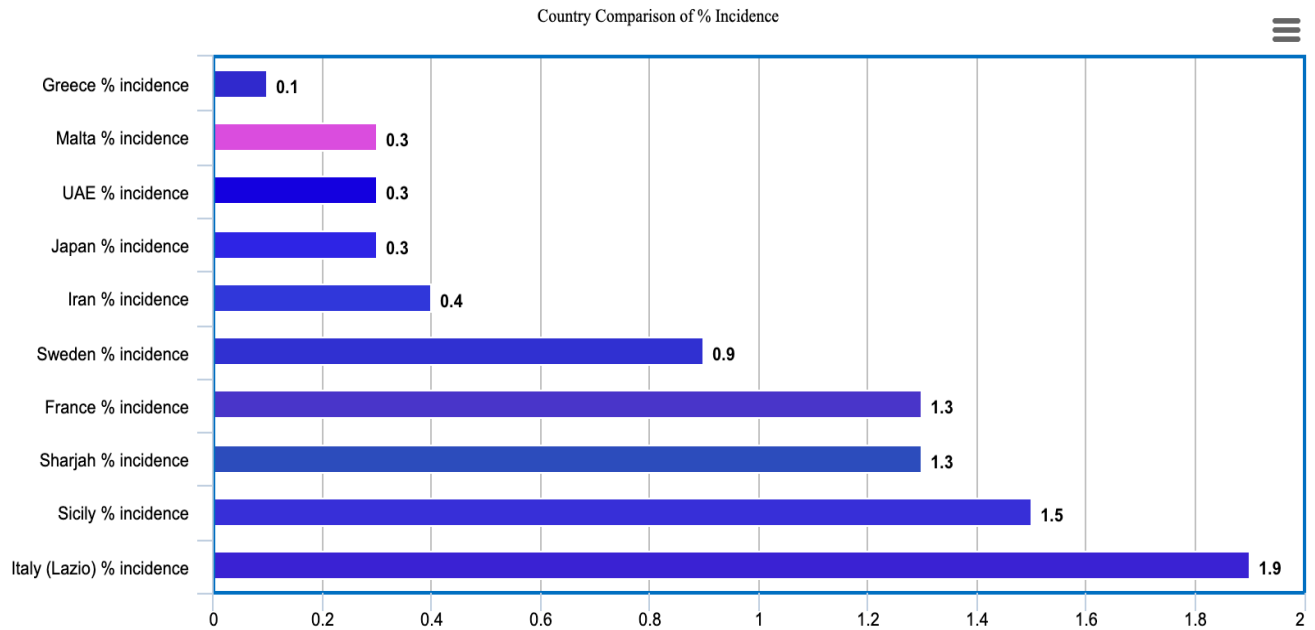


Figure 2. Chart of comparison of incidence by country as extrapolated from literature review.

Malta seems to take its place in the statistical map by being on the higher end of incidence within Europe and on the lower end when compared to Asian and African data. Being an archipelago of islands strategically in the heart of the Mediterranean with a population heavily driven by migration through the ages, we bear similarities to both ends of the spectrum, both culturally as well as regards to healthcare statistics.

Of all the reviewed publications, none reported a rate higher than 1.7%. It should however be noted that there were comparatively less publications relating information on neonatal screening and prevalence of neonatal hearing loss originating from the African, South American and Australian continents. Indeed most sourced studies available for review, which in their own respect are of great benefit, are published in Europe or the Middle East (Papacharalampous, 2011).

At a global incidence of 1.5-3 per 1000 live births (Sequi-Canet & Brines-Solanes, 2021), it is estimated that currently there are 34 million children globally suffering from disabling hearing loss, most of whom are believed to live in South Asia, Asia Pacific and Sub-Saharan Africa. WHO

indicates growing numbers of hearing-impaired children and concerns as the world population grows (WHO, 2018).

An interesting publication by Neumann et al. raises concern that despite the WHO declaring a need for worldwide hearing screening in 1995, by 2020 less than 40 countries report appropriate screening being carried out (Neumann, 2020). Whilst there is no indication to what extent of the global population is covered by these 40 countries, we are still far from the ideal. Without doubt, prior to publication of the latter article, Malta was one of countries which unfortunately was not part of the successful cohort. This study was done with the determination to change that, for good.

The ultimate success of the neonatal screening program is dependent on a multitude of factors, ranging from governmental funding, socioeconomic status of patients, standard of living of the country itself (richer vs. poorer countries irrespective of level of expertise available), multidisciplinary cooperation between different professionals, parent cooperation, neonate comfort and hence cooperation, the available facilities and manpower, and overall sustainability. A lack of regard or a problem in any aspect, becomes a problem of all (Uhlen, 2020; Sambah, 2020; Busse, 2020).

A proposed proforma for improvement would be one that includes gender, mode of delivery, gestational age at delivery and parental history. It would also be interesting to distinguish the results of mainland Malta from that of the rest of archipelago, to investigate whether there is any difference within the same country. As previously mentioned, it would also be of benefit to have an online proforma which is completed by prompting and is backed up, to avoid human errors such those of omission.

### ***Conclusion:***

Early diagnosis and intervention are the main keystones to an excellent outcome. The outcome in the context of neonatal hearing loss may be defined as the assurance of a good quality of life and timely developmental milestones by ensuring that a child with diagnosed hearing loss



receives appropriate adjuncts and rehabilitation at the earliest. The statistics of the Maltese islands reflect global trends. This bears witness to the convenience in following trends, advancements and criticism of the global neonatal hearing screening protocols to ensure a healthy future to our little humans. This pilot project was a good foundation for the Maltese Islands to continue building upon, and sets a guide towards founding a stable local protocol which can be translated to an established national screening program, as well as opening up an opportunity to re-audit at a later stage.

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***Disclaimer:***

This study has received no funding and was not sponsored in any way, shape or form by the NHS, governmental and private institutions or any commercial body. The author declares no known conflict of interest. The study was conducted purely for the benefit of gaining new knowledge on local trends and aims to set a precedent for further work in the concerned fields. There is no intention to monetise this research.

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