

# Malta Medical Journal



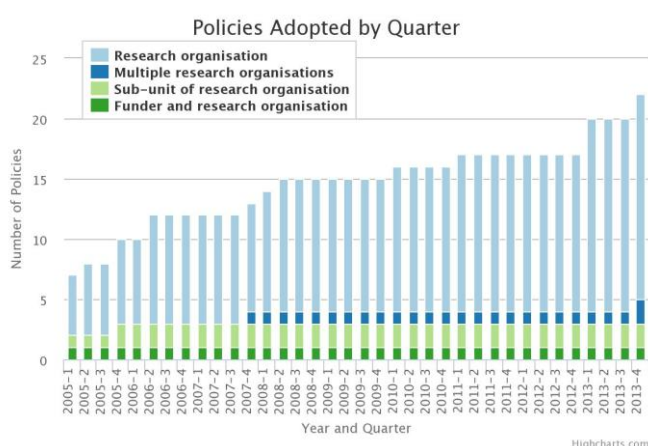
# Open Access Policies: Aligning Strategies and Services

Birgit Schmidt

## Introduction

Early on in the new millenium, institutions began to invent policies which aimed at maximizing access, dissemination and (re)use of research results via open access. Open access makes research findings available free of charge to readers and is a core element of open science strategies, e.g. those of the European Commission. Since then open access policies have been steadily growing in number, with now a total of over 600, some of them already the second or third iteration (cf. Figure 1)<sup>1-3</sup>

**Figure 1. Open access policies world-wide**



However, what is the rationale for an institution to care about open access policies and their implementation? On the one hand there are certainly already enough regulations and institutional agendas, on the other, such a policy can be a good instrument to formulate a common goal and to set a framework for actually achieving this goal. Such a policy will need to involve a wide range of stakeholders to be successful: in particular researchers, research managers and administrators, and librarians. To not unduly increase the administrative burden or create confusion alignment with existing funder mandates is advisable. Most prominently, the European Commission's Open Access Mandate<sup>3</sup>, and national policies need to be taken into account.

Core questions for setting up and implementing an open access policy are:

- Who is responsible for the implementation, what actions are expected from whom?

- How strong is the policy (e.g. an encouragement or a mandate)?
- How is the progress assessed, and by whom?
- What resources are available to support the implementation of the policy, e.g. human support (research administrators, librarians), infrastructure, a fund to support open access publishing?

On the cost side, human resources for making open access happen have been estimated: on average, the green route accounts for about 48 minutes staff time (author and administrators) while the gold route takes about 2 hours (varying from 40 minutes to over 5 hours) – the latter also due to the fact that processing invoices needs a lot of tracking on the side of institutions and processes on the side of publishers need further streamlining.<sup>4</sup>

## Stakeholder viewpoints

Researchers make their choice on what, when, and where to publish, based on their preferences such as outreach and impact, and their experiences with the respective journal or publisher. In these decisions, open access might be factored in but typically only plays a minor role, with less than every second respondent (45%) in a world-wide survey conducted by the EC-funded Study of Open Access Publishing (SOAP) project felt this factor either “important” or “extremely important”.<sup>3</sup> Most recently, based on the growing number of funder mandates, researchers and support staff such as research administrators and librarians increasingly need to be aware what options for open access are available.

The Wellcome Trust, a large UK-based science funder, set up an open access policy already in 2006, followed by a data policy in 2007. The open access policy mandates deposit in Europe PubMed Central (formerly UK PubMed Central), a disciplinary repository co-funded by about a dozen research funders. In addition, funded researchers are encouraged to publish their peer-reviewed articles, books and book chapters via gold open access routes, the costs being met by the Wellcome Trust in addition to the funds allocated to the project for research purposes. How do these articles reach the repository? Typically, articles are deposited by journals and publishers, and a small share by researchers themselves. The OA mandate is certainly

one of the most successful ones world-wide, with a compliance rate of c 70%, up from c 55% in March 2012 when a stricter enforcement was introduced. The sanctions introduced by Wellcome include a measure to withhold the final 10 per cent of the total project budget that will only be transferred as soon as all papers comply. Robert Kiley, Head of Digital Services Wellcome Library and Wellcome Trust, reported that by mid-March 2015 the final payment on grants has been withheld on 111 occasions (44 times on 2013, 48 times in 2014 and 19 times so far in 2015). This policy has resulted in a spend of about £3.9 million in 2012-13 and just under £4.7 million in 2013-14, on average £1,241 for fully OA articles, and £2,030 for articles in hybrid journals (i.e. article-wise open access in subscription-based journals). However, despite these high payments some journals do not offer what they are paid for, and as a consequence several articles are not yet available in Europe PMC and/or are published under a different license than the mandatory Creative Commons CC-BY license. Overall, only 61% of all articles of the period under review are fully compliant.<sup>5</sup>

When it comes to institutional policies, a recent survey among European University Association (EUA) members (106 responses of 783 members, i.e. 13.5%) found that 9 in 10 universities either have an open access policy in place, are in the process of developing one or are planning its development.<sup>6</sup> Encouraging researchers to deposit their publications in an institutional or shared repository is the main element of their OA policy for over 3/5 of all responding institutions. Eight in ten universities have an institutional or shared repository in place. It is unsurprising that the barriers highlighted by respondents include concerns about copyright and uncertainty about publishers' self-archiving policies.

One strategy to secure high deposit rates in repositories is to combine the upload of author manuscripts with research reporting – which can be very successful, as the full text rate of over 80% at University of Liège demonstrates. However, a smaller share of 37% is available in open access. To fill this gap the „immediate deposit / optional access“ principle encourages researchers to deposit their articles immediately at the time of publication, and if an access embargo applies the author can be contacted via a „request-a-copy-button“ (who in turn pressed a button to grant access). Another success story is certainly the OA policy of CERN, the European Organization for Nuclear Research. CERN is committed to open access and collect preprints of most of its research output. In addition, the agreements of the SCOAP3 initiative have converted journals in the field high-energy physics articles to open access, at no costs for any author worldwide. With a status at present at about 90-95% in 2015, and supplemented by central funds and agreements the aim is to reach 100% OA by the end of

2016.<sup>7</sup> At the University of Göttingen, the goal is less ambitious: since 2005 an encouraging OA policy has been in place which is based on support and infrastructure provided by the university library. The Electronic Publishing department combines advocacy activities on the institutional, national and international level, provides access to publishing services (repositories, a university press), manages a publication fund and agreements with publishers and provides information and consulting services. Most recently, the launch of the research data policy (as of August 2014) has been helpful to also add open access to the agenda of large collaborative projects which are asked to develop a strategy for research data and OA to publications. In addition, collaboration between the research office and the library is instrumental for supporting the implementation of the OA mandate of European Commission.

Publication funds are emerging in several countries, often based on co-funding by major research funders, e.g. via block grants of the research councils in the UK, the German Research Foundation (DFG) or the Norwegian Research Council. These funds come with rules set by the main sponsor – which may include price caps and in some cases the exclusion of hybrid journals (e.g. Germany, Norway). Aggregating data across 23 German institutions, it turns out that a median amount of about 1,200 EUR has been paid per article for an overall 3,064 articles in 2014. Some of these institutions have already set up additional agreements with faculties and topped-up the publication fund to cover a larger amount of articles, allow fees beyond the price cap and/or exceptions of other kind. A question still to be solved is the sustainability of the publication funds as the co-funding of the DFG is limited to a 5-year funding period.

Ideally, these stakeholders are not just the core target of the open access policy but the main advocates for securing its success, as only then the benefits of open science will be fully realized.

### National Strategies and Alignment

National policies typically set common rules while also promoting a specific joint strategy for open access. In the UK, since the publication of the Finch Report, the goal is clearly to push for the gold OA route. Since 2014 the Netherlands are also taking further measures to establish the gold route as the major instrument to realize open access. Other countries, such as Ireland and Portugal rely more on the green OA route – not least for economic reasons – with a mature established repository and research information infrastructure in place. The EC's Communications of July 2012 asked EU Member States to further develop and align their open access policies. Results of PASTEUR4OA show that all Nordic countries have already aligned their OA policies with that of the EC, 75% of the countries within South

Western Europe, 43% within the North Western Europe and 33% within the Eastern European region.<sup>8</sup>

Findings of PASTEUR4OA verify that there is a significant correlation between deposit rates in repositories with clauses in open access policies, i.e. those that express a mandatory nature: „must deposit“ or „cannot waive deposit“. In addition, there is a significant correlation between deposit rates and research evaluation, however, these full-text deposits are not necessarily openly available.<sup>2</sup>

### Conclusions

Although open access policies are already widely established and have proven to be effective there remains work to be done: through improved advocacy and support as well as via removing obstacles in the scholarly communication and publishing system. Publishers are offering a wide range of open access publishing options today, but remain very cautious about immediate green open access deposits in repositories. Elsevier's recent change of its sharing policy, was denounced by the library and research infrastructure community demanding Elsevier to revise it.

After ten years' experience of open access policies, one can conclude that such policies need constant monitoring and rethinking of strategies, in particular for involving crucial stakeholders. Links between policies, e.g. for publications and data, and principles for good research conduct can play out well if policies are aligned and offer benefits not just another burden to the researcher. When research groups start to engage with the policy and translate it to their own situation as well how to make the best use of available support and resources this is a crucial step towards regaining control of scholarly communication in the spirit of open science.

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### Cover Picture:

‘Salt Pans’

*Watercolour*

**By Bertha Darmanin**

Bertha was born in 1954 and works within the Faculty of Health Sciences, University of Malta. She studied art privately with local artists and attended various courses set up by foreign artists. She participated in a number of collective exhibitions and her works may be found in both local and foreign locations. Her preferred medium is watercolour.

# Spirometry in Fuel Station Attendants: a Comparative Study

Jacob Vella, Manwel Borg

## Abstract

**Introduction:** Exposure to volatile fuel compounds and roadway motor vehicle exhaust leads to increased risk of chronic lung disease and carcinogenesis. Tobacco smoking further accelerates this process. Spirometry is an objective way of assessing lung function.

**Aims:** To infer whether fuel station attendants manifest a further decrease in lung function when compared to other full-time workers working outdoors and whether smoking tobacco manifest a further decrease in lung function among attendants.

**Methodology:** Lung function of 30 fuel station attendants ( $28.6 \pm 6.24$  years) was compared to 30 outdoor workers ( $27.53 \pm 5.59$  years) as control group via spirometry. Half of both exposed and control group consisted of participants who smoke tobacco.

**Results:** A statistically significant decrease in  $FEV_1$ , FVC and  $FEV_1/FVC$  ratio in the exposed group when compared to the control ( $FEV_1$   $78.84 \pm 7.19\%$  of predicted vs  $87.97 \pm 8.32\%$  of predicted,  $p < 0.001$ ; FVC  $85.84 \pm 7.00\%$  of predicted vs  $90.24 \pm 9.41\%$  of predicted,  $p = 0.02$ ;  $FEV_1/FVC$  ratio ( $76.28 \pm 4.72\%$  vs  $81.15 \pm 4.31\%$ ,  $p < 0.001$ ).

**Conclusion:** Fuel station attendants who smoke showed a significant drop in lung function when compared to non smoking attendants ( $FEV_1$   $75.38 \pm 4.31\%$  of predicted vs  $81.74 \pm 8.18\%$  of predicted,  $p = 0.006$ ; FVC  $89.93 \pm 5.43\%$  of predicted vs  $88.75 \pm 7.34\%$  of predicted,  $p = 0.01$ ).

## Keywords

petrol pump workers, pulmonary function test, occupational hazards, tobacco smoking

## Introduction

Air pollution is an ever increasing hazard due to the rapidly increasing number of motor vehicles. In Malta, with about 314,510 registered cars by the end of 2012, the demand for fuel stations in the Maltese islands has inevitably increased.<sup>1</sup> Although European policy on fuel compositions have lessened these risks<sup>2</sup>, absence of personal protective equipment (PPE) and tobacco smoking are still factors which add up to health effects caused by volatile fuel compounds and roadway motor vehicle exhaust.<sup>3</sup> The European Environment Agency (EAA) report that Malta is finding it difficult to control dangerous gas emissions with a sharp rise in pollution caused by traffic; in 2012 the island European Union (EU) established limit of nitrogen oxide was surpassed by 0.6 kilotons due to a 10 per cent increase in nitrogen oxides ( $NO_x$ ) recorded in 2012 (EAA, 2013).<sup>4</sup>

The British Thoracic Society Standards of Care Subcommittee Guidelines on Occupational Asthma assert that the predominant hazardous health effects are seen on the lower respiratory system and such effects can be measured objectively via lung function tests in an occupational setting.

The aims of the study were to infer whether fuel station attendants manifest a further decrease in lung function when compared to other full-time workers working outdoors and whether fuel station attendants who smoke tobacco manifest a further decrease in lung function when compared to those who do not.

## Methodology

All participants ( $n=60$ ) were Caucasian males (age  $28.27 \pm 5.66$  years).

The exposed group (EG) were 30 full-time fuel station attendants (age  $28.77 \pm 6.45$  years) were randomly selected from all from the 2013 Malta Resources Authority fuel pump list<sup>5</sup> from the different areas of Malta (Gozo was excluded) as presented on the 2010 Malta Demographic Review.<sup>6</sup>

The control group (CG) consisted of full-time recruits (age  $27.77 \pm 4.80$  years) of the Armed Forces of Malta (AFM) based at the Hal Far Barracks in the southern part of the Maltese island and served various

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outdoor roles around the island.

Both groups were then divided into two subgroups and by service duration:

- **Tobacco smokers** 15 in each group: exposed (EGTS) and control (CGTS).
- **2-5 years service duration** 7 in EGTS and 7 in CGTS.
- **more than 5 years service duration** 8 in EGTS and 8 in CGTS
- **non smokers** 15 in each group: exposed (EGNS) and control (CGNS)
- **2-5 years service duration** 7 in EGNS and 8 in CGNS
- **more than 5 years service duration** 8 in EGNS and 7 in CGNS

AFM participants were approached via convenience sampling, i.e. randomly approaching recruits during daily routine. Fuel pumps were randomly chosen To implement further control on variables, inclusion and exclusion criteria were applied to the accessible population as shown in table 1.

### Instrumentation

The spirometer model utilised was the Spiro-M PC® from Medical Econet GmbH, Germany. This model was then attached to an ASUS Eee PC® netbook via a USB port on which the spirometer software was installed. This setup ensured portability and ease of work.

FEV<sub>1</sub>, FVC, FEV<sub>1</sub> / FVC ratio in each group were grouped in tables so as to create clear descriptive statistics via Microsoft® Excel® . FEV<sub>1</sub> and FVC were converted to a percentage of their predicted value via the *GLI2012 version 3.2.1 build 28* where lung function results are adjusted to age, height and ethnicity of the participants.<sup>7</sup>

GLI2012 also worked out lung function results which were considered as follows according to the percentage of the predicted value:

- normal FEV<sub>1</sub> and FVC 81-120% FEV<sub>1</sub> / FVC >70%
- borderline FEV<sub>1</sub> and FVC 76 - 80% FEV<sub>1</sub> / FVC 66-70%
- abnormal FEV<sub>1</sub> and FVC <76% FEV<sub>1</sub> / FVC <66%

Data collection was done by the researcher between February and May 2014. Consenting participants were instructed on how to use the PFM.<sup>8</sup> The highest records of lung function and the ethnicity, height, age and years of employment were recorded in a Microsoft® Excel® spreadsheet.

A written informed consent was presented,

highlighting the aims of the study; the research process and the choice to stop their participation at any point of the study amongst other measures which ensured anonymity and confidentiality.

Permission from fuel station owners and the officer in charge of the Hal Far Barracks were obtained before conducting research.

The study was also approved by the University Research Ethics Committee (UREC).

**Table 1: Inclusion and exclusion criteria**

Inclusion Criteria	Exclusion Criteria
<b>Both Subgroups</b>	
1. Male	1. respiratory disease and conditions such as asthma, chronic obstructive pulmonary disease, bronchiectasis and lung neoplasms
2. 20 – 45 years of age	2. Previous cardiothoracic and upper spinal surgery
3. Understanding of either Maltese or English	3. Vertebral and thoracic disease and conditions such as ankylosing spondylitis and sever thoracic kyphosis
4. Ability to comprehend explanations regarding using the peak flow meter	4. Current upper respiratory tract infection, acute hay fever symptomatology or pneumonia
5. Employed for more than 2 years	
<b>Tobacco Smoking (TS) Subgroup</b>	
1. Currently smoke more than 15 cigarettes a day	1. Smoke less than 15 cigarettes a day
	2. Smoking methods other than cigarettes and tobacco
<b>Non Smoking (NS) Subgroup</b>	
	1. Smoking 1 to 14 cigarettes on any day of the week
	2. Ex-smoker

### Results

A total of 42 fuel station attendants were approached out of which 3 refused to participate, 6 fuel station owners did not grant permission and 3 were not able to conduct lung function testing adequately. 30 Armed Forces of Malta (AFM) recruits were approached; all consented for participation and

conducted lung function properly. Overall response rate was 83.33%.

10 (33%) fuel pumps were located in the northern region of the island, 15 (50%) in the central part while 5 (17%) were in the southern region.<sup>6</sup>

### Lung Function

Tables 2 through 5 show comparison of lung function between groups as follows:

- All exposed (EG) and all control (GG) participants (table 2)
- Smokers and non-smokers (table 3) in:
  - The exposed (EG) group
  - The control (CG) group

- Exposed and control non-smokers with:
  - 2 to 5 years employment (table 4)
  - More than 5 years employment (table 5)
- Exposed and control smokers with:
  - 2 to 5 years employment (table 4)
  - More than 5 years employment (table 5)

**Table 2: Difference in Lung Function between the Exposed and the Control Groups**

<i>N=60</i>	<b>Exposed Group / % n=30</b>	<b>Control Group / % n=30</b>	<i>p&lt;0. 05</i>
<b>%age of predicted FEV<sub>1</sub></b>	78.84 ±7.19	87.97 ±8.32	<b>&lt;0.001</b>
<b>%age of predicted FVC</b>	85.84 ±7.00	90.24 ±9.41	0.02
<b>FEV<sub>1</sub> / FVC ratio</b>	76.28 ±4.72	81.15±4.31	<b>&lt;0.001</b>

**Table 3: Intergroup difference in lung function between smokers and non-smokers**

	<b>Exposed Group n=30</b>			<b>Control Group n=30</b>		
<b>Subgroup</b>	<b>TS / %</b>	<b>NS / %</b>	<b>p&lt;0. 05</b>	<b>TS / %</b>	<b>NS / %</b>	<b>p&lt;0. 05</b>
<b>All (N=60)</b>	<i>n=15</i>	<i>n=15</i>		<i>n=15</i>	<i>n=15</i>	
<b>%age pred. FEV<sub>1</sub></b>	75.38±4.31	81.74±8.18	<b>0.006</b>	89.04±8.81	86.89±7.95	0.24
<b>%age pred. FVC</b>	89.93±5.43	88.75±7.34	<b>0.01</b>	90.63±9.81	89.86±9.32	0.41
<b>FEV<sub>1</sub> / FVC</b>	75.80±2.92	76.76±6.10	0.29	81.63±4.29	80.66±4.42	0.27

**Table 4: Difference in lung Function between smokers and non-smokers with 2 to 5 years of employment**

<b>2-5years n=30</b>	<b>Non-Smokers n=15</b>			<b>Tobacco Smokers n=15</b>		
	<b>Exposed n=7</b>	<b>Control n=8</b>	<b>p&lt;0. 05</b>	<b>Exposed n=7</b>	<b>Control n=8</b>	<b>p&lt;0. 05</b>
<b>%age pred. FEV<sub>1</sub></b>	77.63±5.59	87.26±8.53	<b>0.01</b>	73.86±4.42	92.89±7.28	<b>&gt;0.001</b>
<b>%age pred. FVC</b>	87.29±9.40	88.39±9.34	0.42	82.43±7.30	96.36±8.11	<b>0.003</b>
<b>FEV<sub>1</sub> / FVC</b>	74.64±6.27	83.29±4.01	<b>0.003</b>	76.00±3.58	81.61±4.93	<b>0.02</b>

**Table 5:** Difference in lung function between smokers and non-smokers with more than 5 years of employment

> 5 years <i>n</i> =30	Non-Smokers <i>n</i> =15			Tobacco Smokers <i>n</i> =15		
	Exposed <i>n</i> =8	Control <i>n</i> =7	<i>p</i> <0. 05	Exposed <i>n</i> =8	Control <i>n</i> =7	<i>p</i> <0. 05
%age pred. FEV <sub>1</sub>	85.33±8.67	86.47 ±7.88	0.40	76.71±4.02	85.68±9.06	<b>0.001</b>
%age pred. FVC	90.04±5.29	91.54±8.44	0.34	83.38±3.61	85.61±8.65	0.26
FEV <sub>1</sub> / FVC	78.61±5.68	77.66 ±2.66	0.35	75.62±2.45	81.65±4.00	<b>0.01</b>

**Table 6:** Case-control studies analysing lung function among fuel station attendants  
FSA – Fuel Station Attendants

No	Author / Location	Year	Participants	Cases	Controls	Findings
			FSA's	non FSA		
1	Alam et al. Karachi, Pakistan	2014	160	130	130 unidentified	VC indirectly related to work hours decrease in VC,FVC,FEV1 in cases
2	Sadiqua & Rathna Mysore, India	2012	56	28	28 college personnel	decrease in FEV1 and FVC
3	Sharma, Gupta and Gupta Jammu, India	2012	133	100	33 hospital personnel	decrease in FEV1, FVC, MVV, PEFR
4	Aprajita, Panwar and Sharma Amritsar, India	2011	200	150	50 hospital personnel	decrease in FEV1,FVC,PEFR
5	Madhouri et al. Kanchipuram, India	2010	30	30	30 hospital personnel	decreased FVC,FEV1 and PEFR
No	Author	Year	Participants	Cases	Controls	Findings
				Smoking FSA's	Non- Smoking FSA's	
6	Chawla & Lavania India	2008	58	35	23	a. decrease in FVC,FEV1 and PEF proportion to years of work b. smoking attendants had significantly lower FEV1 only



## Discussion

### Overview of findings

A statistically significant reduction in all lung function parameters, FEV<sub>1</sub>, FVC and FEV<sub>1</sub>/FVC ratio, resulted when comparing all exposed participants ( $n=30$ ) to controls ( $n=30$ ). FEV<sub>1</sub> and FEV<sub>1</sub>/FVC ratio differences were highly significant ( $p<0.001$ ).

Exposed participants, i.e. fuel station attendants (FSAs) showed a decrease in lung function. Mean FEV<sub>1</sub> ( $78.84\pm7.19\%$  of predicted) fell below the normal range (81 – 120% of predicted) and is classified as a borderline result as per the Global Lung Initiative ranges.<sup>7</sup> Mean FVC ( $85.84\pm7.00\%$ ), despite being significantly less ( $p=0.02$ ) than the control mean still fell in the normal range. Mean FEV<sub>1</sub>/FVC ratio ( $76.28\pm4.72\%$ ) is within normal range; however, since FEV<sub>1</sub> is in the borderline range, this would be considered a borderline obstructive pattern of lung function.<sup>7</sup>

Table 6 shows six studies which all report a marked decrease in all 3 lung function parameters. The difference in this study is that FVC seemed not be significantly lower: both when compared to the normal conventional ranges and when comparing groups within the study itself.<sup>9-14</sup>

### Smoking as a contributory factor to a decrease in lung function

Tobacco smokers (TS) and non-smokers (NS) were independently compared in each group.

In the control group (CG), despite a lower mean result in all lung function parameters was registered for TS participants, no statistically significant difference was found when compared to NS control participants and all 3 parameters were in the normal value range.

On the other hand, tobacco smokers in the exposed group (EGTS) showed a statistically significant drop in all 3 lung function parameters when compared to the control group (CGTS). The 3 parameters for EGNS were in the normal range while mean FEV<sub>1</sub> ( $75.38\pm4.31\%$  of predicted) in EGTS was in the abnormal range. FEV<sub>1</sub>/FVC ratio fell in the normal range but since FEV<sub>1</sub> is abnormally low this is to be considered as an obstructive pattern of lung function.<sup>7</sup>

Similarly, Chawla and Lavania<sup>14</sup> compared lung function between 35 FSAs who smoked and 23 who did not. While there was no significant intergroup difference between FVC and FEV<sub>1</sub>/FVC parameters, a significantly lower FEV<sub>1</sub> was registered among participants who smoked. This goes in line with this study.

In light of the above results, fuel station attendants (FSAs) who actively smoke tobacco manifest a further decrease in lung function when compared to FSAs who do not.

### Duration of employment

Results for exposed and control non-smokers, and exposed and control tobacco smokers were stratified by duration of employment: 2 to 5 years and more than 5 years.

#### 2 to 5 years employment

Exposed non-smokers (EGNS) exhibited a statistically lower FEV<sub>1</sub> and FEV<sub>1</sub>/FVC ratio when compared to non-smokers in the control group (CGNS). Since mean EGNS FEV<sub>1</sub> ( $77.63\pm5.59\%$  of predicted) was in the borderline range of values with FEV<sub>1</sub>/FVC ratio being in the normal range, a borderline obstructive pattern resulted.<sup>7</sup>

EGTS showed a statistically significant drop in all 3 lung function parameters when compared to CGTS; the latter had all 3 parameters in the normal range while the former had only FEV<sub>1</sub> in the abnormal range and its difference was of high significance ( $<0.001$ ).

#### More than 5 years employment

No statistical significance was found between non-smokers who were employed more than 5 years in both groups (EGNS and CGNS) and all 3 parameters were in the normal range.

Control smokers had all lung function results in the normal range. Exposed smokers have mean FEV<sub>1</sub> ( $76.71\pm4.02\%$  of predicted) in the borderline range and FEV<sub>1</sub>/FVC ratio in the normal range: both were statistically significantly low when compared to CGTS. EGTS results show a borderline restrictive pattern.

Chawla and Lavania have also found a drop in lung function which is inversely proportion to the years of employment as fuel station attendant; this study has not been able to detect such correlation with those who have worked more than 5 years actually showing a better result.<sup>14</sup> Similarly, Alam and colleagues compared 160 FSAs with 130 unidentified control participants and found that, apart from declining FVC and FEV<sub>1</sub>, vital capacity (VC) also decreased with the number of hours worked in a week.<sup>9</sup>

It is interesting to note that control participants in all studies but one were hospital or college personnel who all classify as indoor workers.<sup>9-13</sup> This study has opted for outdoor personnel and therefore it is assumed that a better control population was chosen since indoor environment could be a confounding variable in all the other studies.

### Conclusion and Limitations

According to the study results, fuel station attendants manifest a further decrease in lung function when compared to other full-time workers working outdoors, and fuel station attendants who smoke tobacco manifest a further decrease in lung function when compared to those who do not.

However, the study carries numerous limitations

with a small sample size being the major one. This study had a very small cohort: 30 exposed participants and 30 control participants. This limited the generalisation of results and also the validity and reliability of statistical data.

The age range of the participants was  $28.27 \pm 5.66$  years – this means that the sample does represent the whole population of fuel station attendants. A narrow age range, despite helping internal validity, was not enough to give as much validity as when participants are matched.

Observer and operational bias might have occurred since the researcher was the only individual involved in the whole process that is data collection, analysis and interpretation.

The study was compared to overseas studies in non-EU, developing countries (India and Pakistan); a comparison with European (or better, local) studies would have given a better interpretation should such other studies been available.

The Southern region of Malta was underrepresentation vis-à-vis number of FSAs where only 5 out of 30 were from the region. The results might therefore not be generalisable in that region of Malta.

Finally this was one of the first experiences of the research in both spirometry and statistics; moreover time restraints, lack of access and resources have definitely impacted the robustness of the results.

Therefore the results cannot be generalised to the study population. However, it can be suggested that fuel station attendants might have worse lung function when compared with other outdoor workers and that tobacco smokers further deteriorates lung function.

### Recommendations

As a result, the study limitations and the poor availability of other studies on the topic should encourage further research in the field. This should especially be the case locally now that a baseline study has introduced the professional community with an idea of the needed awareness, policy and legislation related to fuel stations attendants (FSAs).

### Sole use of Automated Fuel Pump – the way of the future?

In the opinion of the researcher, and in line with the large study that Lynge and colleagues conducted in Scandinavia, having more automated fuel pumps will prevent the long hours of exposure to FSAs.<sup>3</sup> In reality, and in light of the health hazards that a FSA faces, this job can be made redundant as in many regions in first world countries since every motor vehicle driver can operate an automated pump.

### Research Recommendations

Apart from this, the remaining recommendations

address the research community with the following recommendations:

- Conducting the same study with a larger sample.
- Conducting an adjunct questionnaire on symptomatology which relate to disease reflected by a drop in lung function (e.g. asthma).
- Study the effect of other respiratory hazards apart from the fuel distribution industry.
- Qualitative study looking into the experience of fuel station attendants.

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# Are local guidelines on investigations in children admitted with acute gastroenteritis being adhered to?

Francesca Galea, Marija Agius, Stephanie Mifsud, David Pace

## Abstract

**Aim:** To assess adherence to local guidelines on the investigation of children admitted with acute gastroenteritis.

**Method:** Children admitted to Mater Dei Hospital with a diagnosis of gastroenteritis between December 2012 and February 2013 were selected. Their investigations were retrospectively assessed in relation to the degree of dehydration and the type of management given. Hospital guidelines relating to investigations performed in children admitted with gastroenteritis were reviewed and compliance was assessed.

**Results:** A total of 411 investigations were carried out in 76 children with the most common investigations being serum electrolytes, urea and creatinine and random blood glucose. Guidelines were met in 4/76 (5.3%) of the study population. Serum electrolytes had the greatest impact on management.

**Conclusion:** The local guideline on gastroenteritis is not being adhered to in the vast majority of cases. There is an urgent need to raise awareness about the availability and utilisation of this guideline amongst doctors working in paediatrics.

## Key words

Gastroenteritis, Paediatric, Dehydration, Electrolytes.

## Introduction

Acute gastroenteritis is defined as the occurrence of at least 3 episodes of loose watery stool and/or at least 2 episodes of vomiting in the preceeding 24 hours.<sup>1</sup> It is a common, usually self limiting, easily transmissible disease.<sup>2</sup> The commonest causes are viral pathogens with Rotavirus being identified as the leading cause of childhood gastroenteritis across the world especially in children under the age of five years.<sup>3,4</sup> Gastrointestinal fluid losses place children at risk of dehydration, with clinical signs usually being apparent when 3 - 5% of the body weight is lost. Investigation of such patients is based upon clinical judgement and guidance provided by available protocols. This retrospective observational study was performed to assess adherence to the local guideline defining investigations and management of children admitted with acute gastroenteritis.

## Methods

This was a retrospective observational study; the list of patients used was obtained from the register at the Paediatric Accident and Emergency Department at Mater Dei Hospital where the demographic data and provisional diagnosis of patients admitted to the paediatric medical wards are documented. The study cohort consisted of all children aged from 0-<16 years of age admitted between 1<sup>st</sup> December 2012 - 28<sup>th</sup> February 2013. All the children who were documented as having 'gastroenteritis', 'gastritis', 'vomiting' or 'diarrhoea' as the reason for admission were included. The case notes, discharge letters and online results of all these patients were retrieved and evaluated and those who were found to have had another primary diagnosis or who did not meet the diagnostic criteria for gastroenteritis were excluded. The latter criteria were obtained from the local guideline where gastroenteritis is defined as "the

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occurrence of at least 3 episodes of loose watery stools and/or at least 2 episodes of vomiting in the previous 24 hours".<sup>1</sup>

Patient demographics, percentage of dehydration, investigations done, results and any change in management were documented. The percentage dehydration was either found written in the case notes, calculated from the IVI rate or else based on observations documented by the examining doctor. These observations included an assessment of skin turgor, urine output and state of hydration of mucous membranes. These data were then used to determine whether local guidelines on investigation of children admitted with acute gastroenteritis were adhered to and if not, whether there was a particular reason for doing so. The guideline was accessed via the paediatric database available on the local hospital's intranet<sup>1</sup>. The reference ranges of the results were adapted to the study population.<sup>5</sup>

## Results

There were 83 eligible admissions over the twelve week study period. Of these, 7 subjects were excluded due to incomplete or missing data. Of the 76 children included in the study, 55.3% were females and their ages ranged from 0.03 - 15.8 years (mean of 4.39 years). The number of subjects who exhibited clinically inapparent dehydration (0-3%) was 48 (63.2%); 26 individuals (34.2%) had mild to moderate dehydration (>3-8%), and 2 individuals (2.6%) had severe dehydration (>8%) (Table 1).

Four children did not require any investigations. A total of 411 investigations were carried out in the remaining 72 children, as shown in Table 2. The investigations that were most frequently requested were: serum electrolytes in 92.1% (70/76), serum creatinine in 92.1% (70/76), serum urea in 90.7% (69/76), complete blood count (CBC) in 82.9% (63/76), random blood glucose in 60.5%, (46/76) CRP in 28.9% (22/76) and stool cultures in 25% (19/76). The percentage of deranged results was as follows; CBC in 55.6% (35/63), serum urea in 21.7% (15/69), serum electrolytes in 12.9% (9/70), serum creatinine in 11.4% (8/70), random

blood glucose (RBG) in 21.7% (10/46) and C-Reactive Protein in 22.7% (5/22). No microorganisms were cultured from blood cultures, stool cultures or urine cultures when taken. Enzyme immunoassay (EIA) for rotavirus on stool was positive only in one child.

The majority of abnormalities in the CBC consisted of minor deviations from the normal ranges of white blood cell, haemoglobin or platelet count. These were not considered to be clinically significant and had no effect on any of the patients' management. All the deranged blood glucose results were due to hypoglycaemia (<3 mmol/l) however this did not affect the type or rate of intravenous infusion which always contained 5% dextrose (in saline) and which resulted in correction of the hypoglycaemia by the time the result of the blood glucose was available. Abnormal creatinine result impacted management in one case; the creatinine was elevated and a decision was made to keep the patient on intravenous rehydration until the creatinine normalised. Hypokalaemia was detected in 3 cases; hyponatraemia in 4 cases and hyperkalaemia in 2 cases. Serum chloride was low in 1 case. Management was affected in 40% (4/10) of cases. In three cases this was through the addition of potassium supplements to the intravenous fluid to correct hypokalaemia and in one case serum electrolytes were repeated following detection of hyponatraemia on the initial result. No changes in management were effected in the other 6 cases.

The results of microbiological investigations performed on stool specimens were all available after patient discharge and did not affect management. Thirty stool investigations were ordered in all, including stool for the presence of parasites, EIA for rotavirus, stool cultures for the detection of *C.difficile* toxin. Of these only one result was positive and this was to rotavirus.

A comparison of the investigations taken with those stated in the local guidelines on gastroenteritis in children, available since 2007, showed that the guidelines were completely adhered to in **5.3% (4/76)** of the study population.

**Table 1:** Investigations performed in children admitted with different degrees of dehydration

Percentage dehydration	Number of individuals	No investigations done	Only serum electrolytes taken	Other investigations taken in addition to serum electrolytes	Guidelines met
0-3%	48	4	0	44	4
>3-8%	26	0	0	26	0
>8%	2	0	0	2	0

**Table 2:** Total number of investigations taken and impact of abnormal results on management

Investigation	Total	Abnormal (%)	Change in management (%)
<b>Biochemistry</b>			
Urea	69	15 (21.7)	0
Electrolytes	70	10 (14.3)	4 (40.0)
Creatinine	70	8 (11.4)	1 (12.5)
Random blood glucose	46	10 (21.7)	0
Calcium and phosphate	3	1 (33.3)	0
Liver function tests	2	0	0
Venous blood gas	2	0	0
<b>Haematology</b>			
Complete blood count	63	35 (55.6)	0
Coagulation screen	2	0	0
Blood picture	2	2 (100)	0
<b>Immunology</b>			
C-Reactive Protein	22	5 (22.7)	0
Coeliac screen	2	0	0
Thyroid Function Tests	1	0	0
<b>Microbiology</b>			
Stool for parasites	1	0	0
EIA for Rotavirus	8	1 (12.5)	0
Stool cultures	19	0	0
<i>C.difficile</i> toxin	2	0	0
Urinalysis and microscopy	9	0	0
Urine culture	9	0	0
Respiratory screen	1	1 (100)	0
Blood cultures	2	0	0
<b>Imaging</b>			
Chest X-ray	5	0	0
Abdominal X-Ray	1	0	0
<b>Total</b>	<b>411</b>	<b>87</b>	<b>5</b>

## Discussion

The aim of this study was to audit local practices on the investigations taken in patients admitted from paediatric casualty with a diagnosis of acute gastroenteritis. Specifically, adherence to local guidelines was assessed in order to follow on a similar audit carried out in St Luke's Hospital in 2000 looking at routine investigations in acute paediatric admissions.<sup>6</sup> The latter study had suggested an alteration in practice so that investigations be restricted to routine electrolytes alone in those with mild/moderate gastroenteritis.<sup>6</sup> This

then led to the formulation of the current departmental guidelines.<sup>1</sup>

Local guidelines state that in patients with 0-3% dehydration, no investigations are indicated and in patients with mild-moderate dehydration (>3-8%) initiated on intravenous fluids only serum electrolytes need to be taken. In the case of individuals with severe dehydration (>8%) it is advised to take CBC, urea, electrolytes and creatinine, CRP, RBG, venous blood gases (VBGs) and blood cultures.<sup>1</sup> This position is similar to that taken by the National Institute of Clinical



Excellence (NICE) and endorsed by the Royal College of Paediatrics and Child Health (RCPCH) in a guideline published in 2009 relating to diarrhoea and vomiting in children under 5 years of age <sup>7</sup>. The latter guideline was issued 2 years after publication of the local guidelines. However while both guidelines agree over the exclusion of CBC from the panel of investigations where dehydration is mild to moderate, the NICE guidelines suggest that in addition to the serum electrolytes; plasma creatinine, urea and glucose should also be taken if the child is to be started on IVI. <sup>7</sup>

The population of 76 children studied in this audit is larger than that studied in the apriori mentioned audit where the gastroenteritis subgroup was composed of 45 children;<sup>6</sup> this can be attributed to the fact that the time period of data collection was expanded from 6 weeks in the previous study to 3 months in our study.

The guideline on gastroenteritis was followed only in 4 children (5.3%) all of whom had 0-3% dehydration and were started on oral rehydration solution (ORS) without any investigations being taken. In the remaining cases, other investigations in addition to the recommended electrolytes were taken in individuals having percentage dehydration between 0-8%.

With the introduction of iCM (online patient investigation requisition software) and the resultant replacement of hand written blood investigation requests by electronic ones, many doctors ordered a renal function test which incorporates measurement of urea, electrolytes and creatinine automatically in one request. The latter fact however would still not explain the reason why the number of investigations is so high since with the exception of 5 cases; other investigations were taken in addition to a renal function test and the percentage of individuals in whom solely a renal function test was ordered would still be low at 11.8%.

There were no cases in which only electrolytes were ordered; despite the fact that a separate request can be found online on the iCM software. In one case, creatinine and electrolytes were ordered but urea omitted from the panel of investigations.

Of note is that a blood picture result was given in two cases; in both cases the blood picture was reported as showing thalassaemic indices. This was probably an incidental finding; as the lab will automatically work out a blood picture if CBC indices are abnormal; in fact; no documented request for such an investigation was found in the patient notes. However this result did not seem to have a bearing on management as both iCM and the patient notes showed no further investigations or documentation in relation to the abnormal blood picture. A total of 30 stool investigations were ordered in all including stool for culture and sensitivity, stool for *Clostridium difficile* and EIA for rotavirus. Although the results had no immediate bearing on initial management they are important for subsequent management from a

public health surveillance point of view.

With regards to the 'extra' investigations in two cases on whom a CXR was taken, the patients in question were documented as having fever and a productive cough; one patient within the 0-3% dehydration subgroup, in whom CBC and VBGs, were taken was documented as being an insulin dependent diabetic. Urinalysis and microscopy and urine culture were requested on another child who was febrile and whose mother had reported a foul smelling urine. This could argue for the fact that the clinician deviated from guidelines in view of the specific clinical circumstances where other pathologies were suspected in addition to gastroenteritis. The results of the additional investigations performed on these two children were all normal and did not impact management.

While acknowledging the fact that patient investigations and management are also guided by the clinical picture and personal judgement of the assessing clinician, the large number of additional investigations indicates that investigations are being ordered 'routinely' rather than because there is a specific clinical indication to do so. One of the major reasons could be that there is a lack of awareness that such guidelines exist, leading doctors to order a CBC 'routinely' because this is a commonly used investigations. Another reason could be that doctors may decide that once there is a patent cannula in place that is allowing blood letting; one should send bloods for more than one investigation 'just in case' without actual justification for ordering a particular test.

## Conclusion

From this retrospective observational study it was concluded that despite availability of local guidelines explaining which investigations should be taken in children admitted with gastroenteritis adherence is poor at 5.3% with additional investigations being requested even though the results do not have any subsequent bearing on patient management. There is a dire need to raise awareness amongst doctors working in the paediatric department on the availability of guidelines on the management of acute gastroenteritis. Adherence to these guidelines will result in a reduction in the amount of unnecessary investigations that are currently being requested on children and a cost saving to the hospital.

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# Local attitudes in the treatment of low prognosis head and neck squamous cell carcinoma

Herman Karl Borg Xuereb, Anthony Dimech, Kenneth Muscat

## Abstract

The incidence of head and neck carcinoma in Malta is 2.44 per 100,000 population, with 5-year survival rate of 20%. International studies have however shown that head and neck squamous cell carcinoma (HNSCC) carries an average 30% survival rate. The cost of treatment of low prognosis HNSCC patients in Malta is roughly €62,500 per year per person and considering that 7 patients out of those diagnosed are treated curatively annually, the total cost would increase to nearly half a million Euros per annum. In view of this, one is bound to ask the question whether not treating patients with a 30% survival rate is justifiable, especially in view that surgical and oncologic treatment can result in severe disfigurement and poses great physical and psychological stress on patients. No studies about local decision-making with respect to HNSCC have been published. This study set out to explore this issue from the ethical point of view, taking into account a number of variables with respect to treatment and the patient factors. A pre-determined set of questions was formulated and these questions were tackled by ten medical professionals, nine of which had direct contact with HNSCC patients. Issues such as informed consent, old age, quality of life, social variables, autonomy, healthcare rationing, medico-legal problems and past experiences with patients have been identified and discussed with reference to the local situation. It was noted that the majority of interviewed professionals (70%), still emphasised the need to provide full treatment for low prognosis HNSCC.

## Keywords

Ethics, squamous cell carcinoma, head and neck cancer, decision making.

## Introduction

Head and neck malignancy is the sixth most common cancer in the world. Head and neck squamous cell carcinoma (HNSCC) is the most frequently encountered type. The incidence of head and neck carcinoma in Malta is 2.44 per 100,000 population with 5-year survival rate of 20%,<sup>1</sup> although several studies have shown that HNSCC generally carries a 30% survival rate.<sup>2-4</sup> The TNM staging method is used by many clinicians to determine the aggressiveness and severity of cancer, on which a treatment plan can be devised from established protocols. However, the Western world tends to be more legally and scientifically oriented and often finds difficulty in taking ethical moral decisions in such cases.<sup>5</sup>

Although decisions with respect to head and neck cancer are not very different from the ones taken for other cancers, a differentiating feature is that head and neck cancers tend to present late and they would entail radical surgery with subsequent disfigurement and dysfunction which significantly impinge on the quality of life of the sufferer. Several factors need to be considered when it comes to decision making, including informed consent, counselling, treatment withdrawal, end-of life issues as well as the patient's personality, social, cultural and family background.

Health care in Malta is limited by its budget. This leads to prioritization and rationing in health care, whether this being implicit or explicit.<sup>6</sup> One also has to keep in mind the direct (medications, services, therapies, tests, etc.), indirect (productivity, disability, etc.) and intangible (often psychosocial) costs of health.<sup>7</sup> Based on breakdown cost calculations, if one considers all medical personnel involved in the care of HNSCC patients and adds up routine costs of procedures, hospital stay and follow up, a conservative estimate for treating a single HNSCC patient in one year would be around 62,500 Euros.

Social justice including the fair distribution of health care resources is possibly the most important issue in bioethics.<sup>8</sup> Access to health care across borders,

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poverty, age and ethnicity are all important to consider when planning health care distribution. Fortunately, poverty is not much of an issue for Malta since everyone is entitled to free health care, irrespective of his social status. Age discrimination can be a problem as seen in the Britain, where age is given importance with respect to treatment provision.<sup>9</sup> In recent years, Malta has seen a significant influx of irregular immigrants which posed a new challenge for our country. Other minority groups such as the homeless face similar problems in that they tend to get marginalised by the people with consequent social, political and possibly health detriments.<sup>10</sup>

Two models of care representing the two extremes of modern day medical practice can influence decision-making, management and the doctor-patient relationship. These are ‘*evidence-based medicine*’ and ‘*patient-centred medicine*’. Evidence-based medicine integrates the best clinical knowledge of a medical practitioner acquired through experience and clinical practice with current evidence-based medicine in the care of individual patients.<sup>11</sup> This approach tends to disregard the individuality, emotions and preferences of patients in the decision-making process.<sup>12</sup> Patient-centred care takes into consideration the patient as a person with his or her individual ideas, emotions and expectations, and merges these aspects with a common goal in terms of care, health promotion and enhancement of the doctor-patient relationship.<sup>13</sup>

### Methodology

When compared to other countries, the number of medical professionals involved in the management of HNSCC in Malta is small. In this study, a set of qualitative face-to-face video-recorded semi-structured interviews were created. In these interviews, the interviewee had to identify himself before being asked a set of 14 open-ended questions in sequence (Table 1). Both Maltese and English versions were available. The subjective and elaborated responses were then recorded digitally on a laptop computer. These were later transcribed and the data analysed.

The interviewees were all hospital-based professionals, and all the interviews were conducted on hospital grounds. Each was provided with three documents. The first served as a general introduction to the study, the second was a consent form and the third consisted of the questions to be asked. All interview recordings were deleted once the replies were analysed.

**Table 1: Questions asked during each interview**

Interview questions	
A	Do you think the subject has been explained adequately to you?
B	Do you think it is relevant to the local setting?
C	How often do you see such cases per year?
D	Do you think it is ethical to withhold treatment for low prognosis Head and Neck cancer patients and only offer palliative treatment?
E	Yes/no: on what grounds?
F	In your experience is the amount of suffering incurred by the patient during and after the treatment justified?
G	Do you think that the expense incurred by treating these patients is justified where the same money may be used for other groups of patients with a better prognosis?
H	How expensive do you think the treatment of one patient might be?
I	God forbid, if you had to be in such a situation what type of treatment if any would you prefer?
J	Should you be involved in this decision making process?
K	Do you think you are involved in the decision making?
L	In your experience do you recall any specific patients in this prognosis group who unexpectedly fared really well or really badly?
M	Did these episodes affect your clinical decision making vis a vis the management of subsequent patients?
N	Any further comments?

### Results

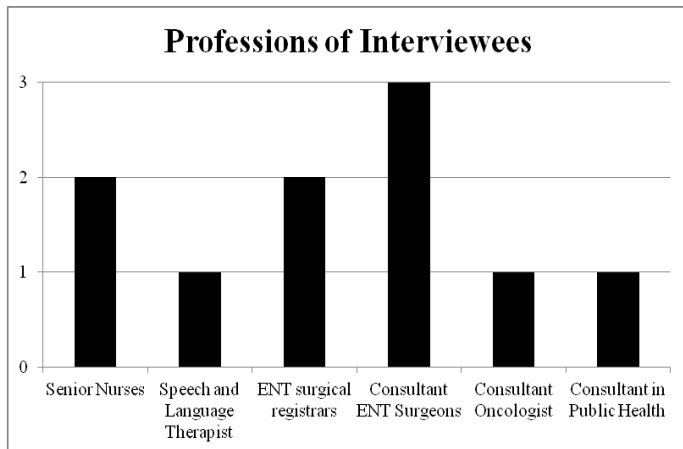
10 medical and para-medical staff (7 males and 3 females) were interviewed, with a mean age of 43.7 years (29-53 years). Their respective professional backgrounds are displayed in Figure 1, and the mean professional working years was 20.6 years. Each interview lasted a mean of 12 minutes. Nine of the professionals interviewed had direct daily contact with HNSCC patients.

Figure 2 shows the results of nine of the eleven questions that were asked. With respect to Question C, the mean incidence of HNSCC estimated by the respondents was 11.7 cases per year.

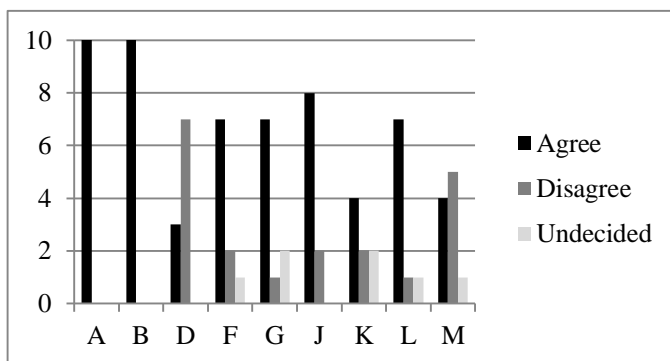
When asked whether or not it would be ethical to withhold treatment for low prognosis Head and Neck cancer patients and only offer palliative treatment (Question D), which is central to this study, 3 agreed to

withhold treatment and 7 considered this decision unethical. However, 7 respondents emphasised that informed consent should always take priority.

**Figure 1: Professions of interviewees (n=10)**



**Figure 2: Responses to nine of the eleven questions asked in the interview. Answers to Questions C, E, H, I, J and N were more elaborate and the data could not be adequately presented graphically**



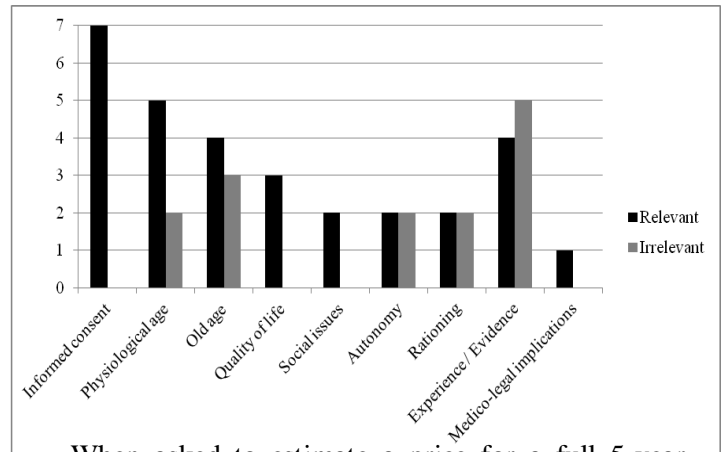
Regarding Question E, of those who would **withhold treatment**, one mentioned that although the patient should preferably take part in the decision-making process, this may not be true in all cases. For example when the patient has a low IQ or other co-morbidities interfering with the treatment plan, the doctor may decide for the patient. One also argued that patients would endure much suffering if administered the full treatment, so might as well opt for palliative care alone.

Seven medical professionals emphasised the need to **provide full treatment** for low prognosis HNSCC. One based his reasoning that a prognosis of 30% is very much similar to other types of cancers which would normally still merit treatment. Two interviewees pointed out that the patient should be looked at and treated holistically and not only from the cancer point of view. Another interviewee stated that every patient is entitled to treatment because we do not know who will survive or not, and one should never consider the social value of the patient when it comes to deciding to opt for surgery

or not. Finally, the need to avoid providing the patient with falsely high expectations was brought up.

When asked to elaborate further on their answer to Question E, a number of considerations were mentioned by the interviewees and are shown in Figure 3.

**Figure 3: Incidence of considerations as mentioned by interviewees when asked to elaborate on their answer to Question D**



When asked to estimate a price for a full 5-year treatment of a patient with HNSCC (Question H), a mean price of €37,222 was quoted (range €10,000-€100,000). One interviewee could not estimate a price.

Question I placed the clinical profession in the patient's seat. Three would accept the full treatment, two preferred palliative care, four were undecided and one preferred not to be treated. Many argued that there were a lot of variables that needed to be considered, mainly age and social issues such as family.

When asked to provide further comments, eight of the interviewees agreed that patients form an important part in the decision making process and that multidisciplinary teams (which are lacking locally) are of utmost importance in the holistic management of patients. There was the need of standard paramedical protocols and audits aimed at assessing survival and quality of life. Furthermore, the more experienced surgeons tend to favour conservative treatment.

## Discussion

Question D was by far the most important, and on which this study is actually based. The responses were essential for evaluation of the local decision-making process. In some situations, informed consent requires care and skill to be extracted properly. However, it is close to impossible to explain all the outcomes so that the patient can make a truly informed choice. Being faced by a distraught patient does not help either. Sometimes doctors try to soften the blow by putting some details aside. Furthermore, many times the relatives direct the physician on what to say, when and how to say it.<sup>14</sup> This has been the norm for many years, whereby non-disclosure of sensitive information to the

patient regarding serious or terminal illness was considered taboo.<sup>15</sup> On the other hand, safeguarding the right to autonomy is a prerequisite in showing respect for human integrity.<sup>16</sup> Combining disclosure with autonomy requires good negotiation techniques, merging the physician's medical knowledge with the cultural factors underlying the family's and patient's views.<sup>17</sup>

Physiological age was considered more important than old age by the majority of interviewees. This is understandable as age-related physiological changes and co-morbidities expose the elderly to certain risks. For many elderly patients, it is the way they live their final years that matters most rather than by how many years they can prolong life.<sup>18</sup> A multidisciplinary team may help to improve quality of life of such patients, which is very reasonable in this regard. In addition, psychological interventions which target social support are important in diminishing treatment-related side-effects.<sup>19</sup>

Seeing how a small number of medical professionals are aware of so many ethical issues, one can identify an element of egalitarianism and utilitarianism as well. Decisions are often based on a combination of morals, intuition and evidence-based medicine. Intuition in itself can be useful in some situations, but not so in others.<sup>20</sup> Rationality and consistency may be challenged in the face of a decision harassed by variables such as worry, risk aversion and perception of danger.<sup>21</sup> Traditional healthcare ethics often call for a more paternalistic approach, which may conflict with the modern ethical principles of autonomy and transparency in decision-making.<sup>22</sup>

Expensive interventions have forced doctors to shift their approach from the individual to the wider community.<sup>23</sup> Health responsibility comprises both a personal and a social aspect. This led to the concept of co-responsibility, which indicates the subjects and objects of health responsibilities, and considers responsibility as being different from prioritization of treatment methods.<sup>24</sup>

The element of solidarity in health care is strongly defended and is based on three factors. **Emotional bonds** should exist among interacting members of the group, which are united by **universal goals and ideals**. There must also be an element of **sacrifice** within the group. More recently, the criteria which define solidarity have been extended to include responsibility for health, communal health benefit, acknowledgement of utilitarian ideas which promote the common good and sacrificing one's own care so that others may benefit.<sup>5</sup>

## Conclusion

This paper was part of the first author's Master of Arts in Bioethics at the University of Malta. It portrays

that the majority of professionals interviewed agree that it is unethical to withhold treatment for low prognosis HNSCC patients. However, not treating is by no means not caring. Indeed those who chose not to treat at the outset based their decision on a holistic view of the patient and the possible consequences of the actual treatment, which included more suffering and the risk of giving false hopes. Finally, the principles of the common good and justice ensured that fairness ruled over the distribution of health care resources.<sup>25</sup>

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# Epidemiology and Seasonal Variation of state Hospital Admissions for Bronchiolitis among children in Malta

Frank Christian Casha, Justine Farrugia Preca, Rebecca Pisani

## Abstract

Bronchiolitis is a seasonal viral illness characterised by breathing difficulties, cough, poor feeding, irritability and lethargy and, in the very young, apnoea.<sup>1</sup> General Practitioners (GPs) often encounter children with bronchiolitis and as GPs working in Malta, we noticed certain patterns of infection, such as the young age of this patient group, the increased frequency of occurrence in the winter months and a commonly reported history of Neonatal Intensive Care admission.

We therefore looked for published local literature to determine the local epidemiology of this illness and found none. Review of the international literature led to an understanding of the existence of a specific seasonality of bronchiolitis in the northern hemisphere, with more admissions being recorded in the winter months.<sup>2-7</sup> Particular trends in the demographics of admitted children were noted in the literature, specifically with younger patients, as well as children with previous Neonatal and Paediatric Intensive Care admission being more frequently admitted.<sup>3-5</sup> This retrospective study was undertaken in order to establish whether there is any seasonal variation in the rate of hospitalization for bronchiolitis, what observations could be made about epidemiological factors describing these admissions and their radiographic and microbiological investigation in secondary care.

*Aim and intended learning outcomes:* The aim of this retrospective study was to determine the local seasonality of hospital admission for bronchiolitis. Once determined, the results should aid physicians with diagnosis, referral and appropriate admission, and may guide promotion of vaccines that decrease the burden of vaccine preventable disease.

*Method:* Records of hospital admissions for bronchiolitis among infants or children under two years of age at Mater Dei Hospital in Malta for the four year period covering January 2008 to December 2011 were examined, due to availability of data. Admission data, mainly name and patient identification number, together with basic demographics like locality of residence and dates of admission were collected from the Department of Health Information and Research and was used to identify the recorded cases after obtaining necessary permits from the Head of the Paediatric department at that time and also from the University of Malta Ethics Board. The diagnosis leading to the classification of the admission as one for bronchiolitis was validated by examining a significant sample of the doctors' notes in the relevant patients' files and matching these against clinical criteria for diagnosis.<sup>1</sup> The number of admissions due to bronchiolitis per day was recorded. Each day, with its corresponding number of admissions was put accordingly into one of four groups as shown—Group 1 all days in December, January and February; Group 2 all days in March, April and May; Group 3 all days in June, July and August; Group 4 all days in September, October and November. These were then ranked, and a non-parametric test of significance, the Kruskal-Wallis equality-of-populations rank test, was used to determine whether there was any significant difference between the groups.

*Results:* Our findings show a peak in admissions during the winter months. The median age of admission among children under two years of age was of 16 weeks; 10% had a past history of NPICU admission. 54.4% had a chest X-ray done and 41.6% were tested for causative organisms with a throat swab. Of the 41.6% tested, 19.4% tested positive for the Respiratory Syncytial Virus. The other results of these clinical tests are also described.

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**Conclusions:** In Malta, there is a higher number of hospital admissions for bronchiolitis among infants or children under two years during the winter months. The median age for admission is 16 weeks. Further studies are suggested to establish whether previous Neonatal and Paediatric Intensive Care Unit admission is a risk factor for bronchiolitis in Malta, and appropriately designed prospective studies are suggested to further assess the occurrence of causative organisms. We also suggest that national guidelines be drawn up for use in primary care for the appropriate identification and referral of cases of bronchiolitis, which peaks in the winter months.

## Keywords

bronchiolitis, Malta, respiratory, epidemiology, seasonality

## Background

Bronchiolitis is a seasonal viral illness characterised by breathing difficulties, cough, poor feeding, irritability and lethargy and, in the very young, apnoea.<sup>1</sup> It is the commonest cause for hospitalisation of infants in the developed world.<sup>6</sup> It is a transmissible disease, transmitted through direct contact with respiratory secretions and indirect inoculation from surfaces. It generally presents as a one to two day history of upper respiratory tract symptoms followed by moist cough, respiratory distress and feeding problems once the lower airways are involved. Treatment is mainly supportive and varies from treatment at local clinics intermittently to continuous inpatient treatment and at times ITU care.<sup>6-8</sup>

International studies which depicted seasonality of bronchiolitis showed an increase in admission rate in the winter months<sup>3,4,4-6,8-19</sup> with the months November and March being those in which the highest admission rate was noted in the northern hemisphere. We wanted to determine whether Malta followed a similar pattern.

Common points encountered in many articles also include the age of the infants who were affected. The highest prevalence of bronchiolitis was seen mainly in infants less than six-months old<sup>3,4,11,15-17,19-24</sup> with a decrease in occurrence noted as the infants become older.<sup>14,25-27</sup> An increase in overall bronchiolitis admission rates over the recent years was also noted internationally with some studies quantifying more than a doubling in admission rate in the last 10 years, despite a relatively stable admission rate with other respiratory tract disease like pneumonias or exacerbations of asthma.<sup>4,6,15-18</sup>

A curiosity regarding the local situation arose, in line with the literature read together with patterns, which were noted by us General Practitioners. Henceforth, a study was set up to investigate the matter in question.

## Methods

### *Denominator population:*

All recorded bronchiolitis admissions (as provided by the Department of Health Information and Research) of infants aged 0-2 years admitted to paediatric medical wards at Mater Dei Hospital in the four year period between 2008 and 2011 were included in the study. The date of admission and patient demographics were then recorded.

The identity of all admissions falling under the ICD 10 classification J21.0 to J21.9 was obtained from the Department of Health Information and Research, after obtaining ethics approval and approval from the Head of Department of Paediatrics, Data Protection Officer and Hospital CEO at the time of the study.

Authentication of the criteria for definition of bronchiolitis was done by sampling at random 1 in 15 files of patients admitted, using the method outlined below [see Validation] and verifying that what was classified as bronchiolitis in the discharge letter was in fact bronchiolitis as described in the Scottish Intercollegiate Guidelines Network (SIGN) guidelines, by nature of the relevant clinical features being present.

### *Data collection:*

All cases recorded by the Department of Health Information and Research as having been admitted to Mater Dei hospital for bronchiolitis with ICD 10 Classification J21.0-J21.9 between January 2008 and December 2011 were identified by the corresponding national identity number.

For each of these, relevant available demographic data such as location of residence, gender and age were noted. Any preceding or consequent NPICU admissions, radiographic, viral or microbiological tests taken during admission were also found on the Mater Dei hospital electronic database iSoft [henceforth, iSoft database] and recorded on a purposely designed database.

### *Quality checks and control:*

**Validation:** In order to validate the correct use of the term 'bronchiolitis' in diagnosis and registration on the DHIR database, we randomly sampled a significant number of incidents of hospitalisation for bronchiolitis and the corresponding patient records (hospital files) were examined to check if the clinical features noted during the hospital stay were compatible with a clinical diagnosis of bronchiolitis as defined in the SIGN guidelines for bronchiolitis. Random selection of the files involved listing all the admissions chronologically and 1 in 15 files was called for and data was checked.

**Bias:** Since we relied upon data collected by the Department of Health Information and Research, in part gathered through the use of the Electronic Case

Summaries system which came into use in 2008 (usage rate of 60-70% in the first 2 years of use and 85% in the last 2 years) the data for the first 2 years would be subject to bias in detection of cases.

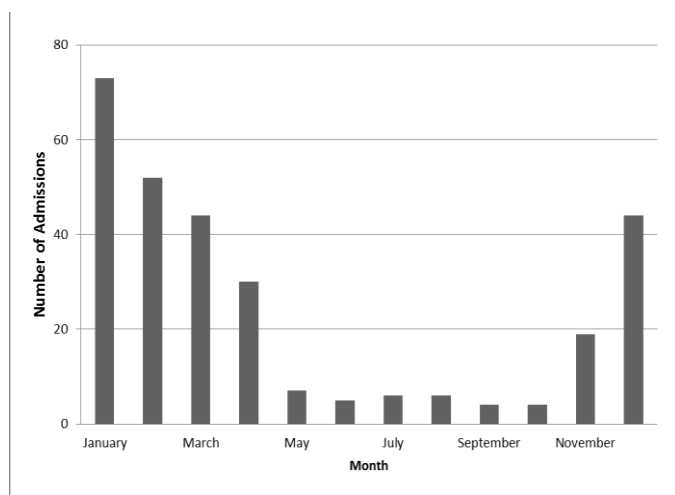
## Results and analysis

### *Age, Gender and Monthly Variation of Admissions: General Observations*

A total of 298 admissions for bronchiolitis were recorded in this period. Of these, 194 were males and 104 were females. The age range of the infants was between 13 days and 82 weeks old. The median age was 115.5 days (16.5 weeks); the first quartile age was 68 days while the third quartile age was 183 days. From the sample taken, we found that 60% had both nasal discharge and cough, 36% had a cough without nasal discharge while less than 0.05% had nasal discharge without cough. Fine inspiratory crackles were present in about 20% of the sampled population while high pitched wheeze was present in 64% of the sampled population. On reviewing the notes of the sampled population, we concluded that the diagnosis of bronchiolitis was in line with clinical guidelines in all cases.

The number of admissions to Mater Dei Hospital due to bronchiolitis during each month between January 2008 and December 2011 is shown in Figure 1. From the graph, it is evident that the number of admissions was higher during the winter months, particularly December and January.

**Figure 1:** Number of admissions per month between January 2008 and December 2011



### Seasonal Differences: Kruskal-Wallis Rank Test

In order to determine whether there is a significant seasonal difference in the median number of admissions, the twelve months of each year were grouped into four categories as follows:

- Group 1: December, January and February
- Group 2: March, April and May
- Group 3: June, July and August
- Group 4: September, October and November.

For every group, each day within the included months was listed alongside the corresponding number of admissions for that day. These were then ranked, and a non-parametric test of significance, the Kruskal-Wallis equality-of-populations rank test, was used to determine whether there was any significant difference between the groups. The null hypothesis was that there is no difference in the median number of admissions between each group while the alternate hypothesis was that there is a significant difference in the median number of admission between each group.

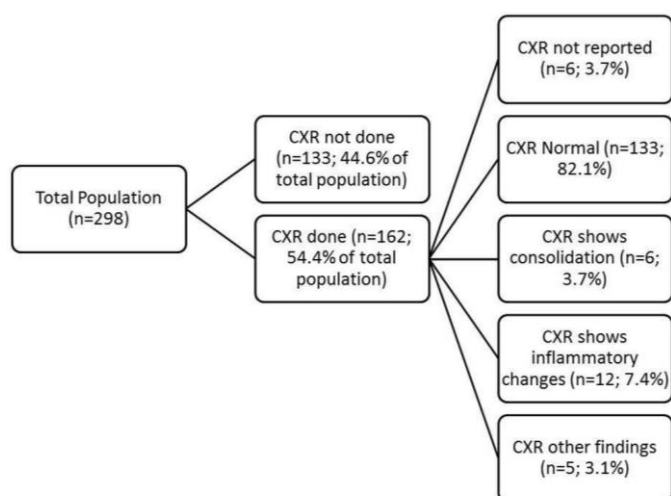
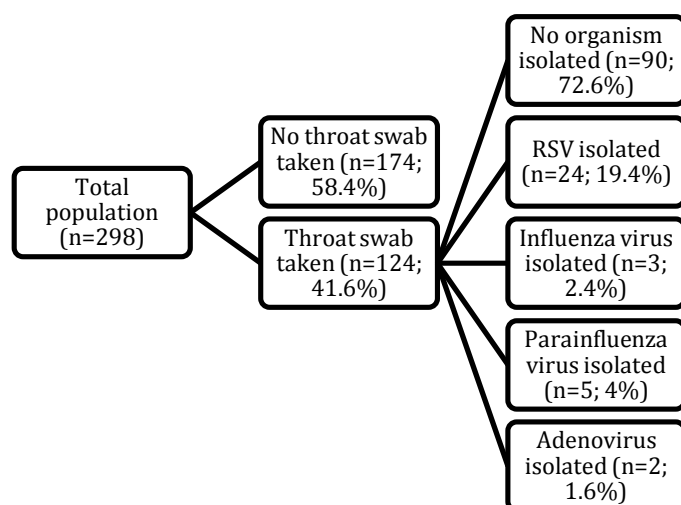
**Table 1:** Rank Sum values for Kruskal-Wallis analysis for the four groups.

Group	Observations	Rank Sum
1	361	316608.00
2	368	272613.00
3	368	237068.00
4	364	241702.00

As expected, the most marked difference in the rank sum was that between Group 1 (December, January and February) and Group 3 (June, July and August). The chi-squared value was 68.197 with 3 degrees of freedom. The p-value was 0.0001. The null hypothesis was rejected and the alternate hypothesis was accepted. In other words, there is evidence that admissions due to bronchiolitis are greater in the “winter” months as opposed to “summer” months. This is in keeping with international observations.

### Investigations during Hospital Admission

54.4% of the total population had a chest X-ray performed. Consolidation was evident in 3.7% of these and inflammatory changes were present in 7.4%. The vast majority (82.1%) were reported as normal by the radiologist (kindly refer to Figure 2). 3.7% of chest x-rays were not officially reported by radiology. 41.6% of the children were tested for causative organisms with a throat swab. 19.4% tested positive for Respiratory Syncytial Virus (RSV), while 2.4% tested positive for the influenza virus, 4% tested positive for the parainfluenza virus and 1.6% tested positive for adenoviruses. In 72.6%, no organism was isolated (kindly refer to Figure 3).

**Figure 2: CXR findings****Figure 3: Isolates from the throat swab****Further observations**

It was recorded that 10% had a past history of NPICU admission. This could not be compared to the international data since we did not acquire data for the years in question describing the local post natal NPICU admission rate and a breakdown of reasons for admission. Furthermore, we could not determine the gestational age at birth of the neonates admitted with bronchiolitis, and so cannot comment on preterm delivery as a risk factor for bronchiolitis. Further studies relating previous NPICU admission to subsequent admissions with bronchiolitis are recommended.

**Summary and conclusion**

In the single state general hospital in Malta, there is a higher number of hospital admissions for bronchiolitis among infants or children aged under two years during the winter months (November to February) in the four consecutive years studied. Locally, a rather stable rate of admission was noted over the years, excluding the single peak in 2008, as opposed to the steady increase over years reported in international literature.<sup>4,6,15–17</sup>

Further studies are suggested to establish whether previous NPICU admission is a risk factor for bronchiolitis in Malta, and appropriately designed studies are suggested to further assess the occurrence of causative organisms. This study will also help highlight the red flags of bronchiolitis in children, especially in primary care, where one can only rely on clinical manifestations.

**Appreciation**

We would like to express our thanks to Dr Neville Calleja and staff at the Department of Health Information and Research for providing data and proof reading our statistics and Dr Jurgen Abela from the UOM faculty of Primary Care, for mentoring the study.

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# Delayed discharges and unplanned admissions from the Day Care Unit at Mater Dei Hospital, Malta

Jessica Sant, Glenn Paul Abela, Daniel Farrugia

## Abstract

**Introduction:** Day care units are playing an increasingly important role in healthcare provision, however they require the development of specialised resources to fulfil their role. The rate of unplanned admissions following day-case procedures is considered as one of several indicators of the quality of day-case services available.<sup>1</sup> The aim of this study is to identify how often there are delayed discharged or unplanned admissions following day-cases at the Day Care Unit at Mater Dei Hospital (MDH), Malta.

**Method:** A list of patients whose discharge did not go as planned was forwarded daily to the authors by the Bed Management Unit at MDH. The medical files of these patients were then reviewed and data collected. This included demographics, type of procedure carried out and reasons for delayed discharge or unplanned admission. The study was carried out over 45 days.

**Results:** 3599 patients were admitted to the Day Care Unit over the study period: 1855 as day surgeries and 1744 as endoscopy cases. 142 were not discharged as planned: 50 patients had their discharge delayed by up to 5 hours and 92 patients required overnight admission following a day-case procedure. This means that 3.9% of all DCU patients were not discharged as planned and 2.6% were admitted overnight. When only taking into account those patients who received a general anaesthetic or sedation in an operating theatre (n=1170), 64 patients (5.5%) were admitted to MDH.

**Conclusion:** MDH has a reasonable rate of delayed discharges and unplanned admissions following day procedures, especially when compared with data from UK hospitals. However, there is still room for considerable improvement.

## Keywords

delayed discharges, unplanned admissions, day case surgery, day case anaesthesia.

## Introduction

Day surgery is defined as “the admission of selected patients to hospital for a planned surgical procedure and the patient returns home on the same day.”<sup>2</sup> It presents a number of advantages over longer hospital stays, including less disruption to patients’ lives, reduced waiting times, speedier recovery, less hospital costs, improved use of theatre lists and more availability of inpatient beds.<sup>3</sup>

Day surgery units thus have a pivotal role to play within the healthcare system. The British Department of Health aims at having 75% of all elective surgeries to be carried out as day cases. However, this has not yet been achieved across UK centres and the present figure stands at 68%.<sup>2,3</sup>

In some instances, patients who are planned to be discharged home on the same day are either kept in hospital for a longer time or may even require an admission. The reasons may be varied but these unplanned prolonged stays may create pressure on the availability of acute beds and may also reflect a suboptimal standard in the management of day-case patients.

The aims of this study are to find out the number of day-case patients whose discharge were delayed or who were admitted to hospital, to identify the reasons for these unplanned events and to recognise patterns of patient movement that may impinge on resources and staffing levels.

## Methodology

Permission to carry out this study was sought from and granted by the Chairperson of the Department of Anaesthesia and Intensive Care at Mater Dei Hospital (MDH), Malta.

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A discharge was considered as delayed when it occurred after 1800hrs on the same day. Some of these patients were kept in the day care unit while others were transferred to an in-patient ward prior to discharge. Patients were considered admitted for an overnight stay if they spent at least one night at hospital.

This prospective study was carried out during the 45 days in which the Day Care Unit (DCU) operated, between March 6th to April 30th, 2014. A list of patients who fell under the above criteria was forwarded daily to the investigators by the Bed Management Unit at MDH. The medical notes were then reviewed to identify patient demographics, type of procedure, reason for delayed discharge or admission and, in the case of an admission, duration of the hospital stay. The time of arrival to stage one recovery, defined as the time of entry to the Post-Anaesthesia Care Unit (PACU) and to stage two recovery, defined as the time of return to the DCU, were noted for all patients.

The total number of patients who were admitted through the DCU and details of the procedure, the anaesthetic and the respective firm were retrieved using the DCU register and the computerized Clinical Patient Administration System.

Data was then inputted and analysed using Microsoft Excel®.

## Results

A total of 3599 patients were admitted to the DCU over the study period: 1855 patients were managed at the day surgery unit and 1744 were endoscopy cases. Further evaluation of the day surgery patients (n=1855) revealed that 820 patients (44.2%) were administered a general anaesthetic, 350 (18.9%) received sedation and 685 (36.9%) only had a local anaesthetic.

During the 45 days over which the study was carried out, there were 7 days in which there were neither delayed discharges nor unplanned admissions.

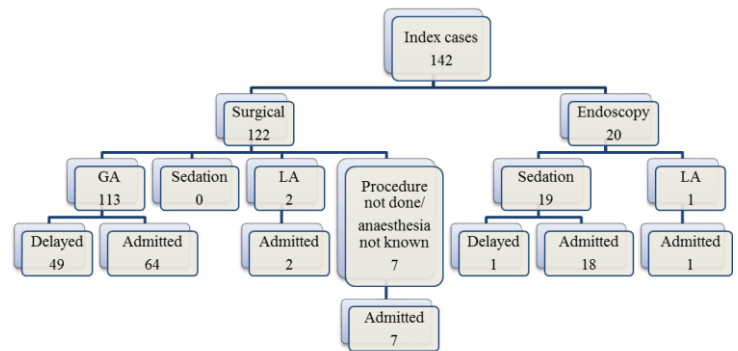
The number of patients whose discharge did not turn out as planned totalled 142; 113 of these patients received a general anaesthetic, 19 received sedation and another 3 had their procedure carried out under local anaesthetic. No data for type of anaesthetic for 7 of these patients was available.

Of the 142 patients, 50 had their discharge delayed for up to 5 hours while 92 patients were formally admitted to hospital. Twelve of these admissions had a hospital stay of more than one night. This means that 3.9% of all the DCU patients (including endoscopy) were not discharged as planned and 2.6% were admitted overnight. When only taking into account those patients who received a general anaesthetic or sedation in an operating theatre ("true day surgeries", 113 cases),

49 (43.4%) had their discharge delayed and 64 patients (56.6%) were admitted to hospital (Figure 1).

**Figure 1:** Flow diagram demonstrating distribution of delayed and admitted patients according to anaesthesia received.

GA: general anaesthesia, LA: local anaesthesia, Delayed: delayed discharges (discharged later the same day after 18:00), Admitted: patients who were formally admitted to hospital for at least 1 night.



This translates into 5.5% of "true day surgery" cases (from a total of 1170 such patients) being admitted to MDH.

Most of the patients who had their discharge delayed or required an overnight stay had received a general anaesthetic (113 patients, 95.6%) and were general surgical patients (including breast surgery but excluding endoscopic procedures) (69 patients, 48.6%) (Table 1). Average age was 55.1 years and gender distribution was equal (71 people for both males and females) (Table 2).

Unfortunately, the reason for the delayed discharge or unplanned admission was not recorded in the notes of 41 patients (28.9%). The reasons for delayed discharge and unplanned admission for the remainder of the patients are listed below (Table 3). It is important to note that some patients had more than one reason for them to have a delayed discharge or needing an admission.

Only the time of arrival to stage one recovery was recorded in enough cases (116 patients) for it to be investigated. The time of arrival to stage two was rarely written down. The number of patients entering PACU every hour is demonstrated in Figure 2. 26% of patients requiring extended stay arrived to stage 1 recovery after 16:00 whereas 19% of patients arrived at stage 1 recovery between 16:01-18:00.

**Table 1:** Case distribution by type of procedure and the anaesthesia used.

GA: general anaesthesia, LA: local anaesthesia

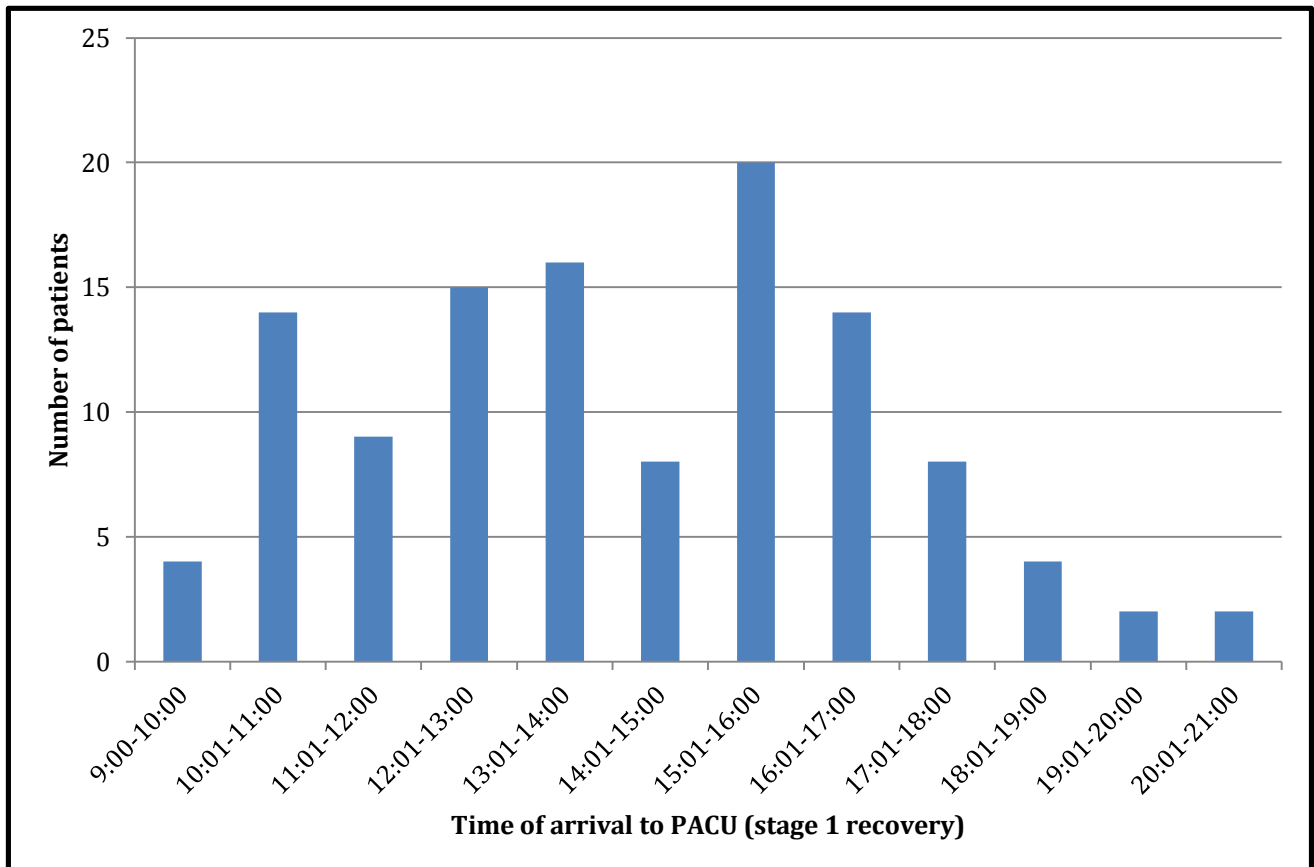
Type of Procedure	Total	GA	Sedation	LA
Endoscopy	20		19	1
Breast surgery excluding general	17	17		
General excluding breast surgery	52	51		1
Gynaecology	16	16		
Orthopaedics	18	18		
Dental	2	2		
ENT	1	1		
Urology	9	8		1
No specialty known	3			
Procedure not done	4			
Total	142	113	19	3

**Table 2:** Case distribution by gender and mean age

GA: general anaesthesia, LA: local anaesthesia

Specialty	Male	Female	Mean age
Endoscopy	10	10	67
Breast surgery excluding general	0	17	59.4
General excluding breast surgery	39	13	52.6
Gynaecology	0	16	52.2
Orthopaedics	7	11	51.9
Dental	2	0	15.5
ENT	0	1	63
Urology	8	1	57.4
Specialty not known	3	0	
Procedure not done	2	2	
Total	71	71	

**Figure 2:** The average number of patients arriving at PACU (stage 1 recovery) every hour.



**Table 3:** List of reasons why patients were not discharged as per routine. Delayed discharges and unplanned admissions are separate. There are more reasons than index cases as some patients had more than one documented reason. TWOC: trial without catheter, BMI: body mass index, PMH: past medical history.

Reasons for patient not undergoing routine discharge from the DCU		Delayed discharge	Admitted	Total
Surgical	More extensive procedure than planned	1	13	14
	Pain	1	10	11
	Bleeding	0	3	3
	Wound packing, etc	0	2	2
	Urine not passed	3	4	7
	For assessment of mobilisation/continuous passive movement (other)	0	3	3
	Check x-ray ordered 1 day post op (other)	0	2	2
	Suspected or confirmed perforation (other)	0	3	3
	Prescription of IV antibiotics post-op (other)	0	3	3
	TWOC (other)	0	1	1
	Need for bladder irrigation (other)	0	1	1
	Patient requiring further in-patient investigation +/- treatment (other)	0	4	4
	Specified by surgeon but no reason documented (other)	0	2	2
Anaesthesia	PONV	3	2	5
	Drowsy	1	1	2
	Abnormal vital signs	1	5	6
	Spinal did not wear off	0	0	0
	Foot drop due to nerve block	0	0	0
Medical	High BMI	0	1	1
	Significant PMH	1	5	6
Social reasons	Social reasons	0	1	1
Patient returned late from theatre	Patient returned late from theatre	11	23	34
None	None specified	29	8	36
<b>Total</b>				147

## Discussion

The Day Care Unit at MDH has favourable rates of delayed discharges and unplanned admissions. This points towards overall good patient management by the personnel involved at all grades, however, there is still room for improvement. The Royal College of Anaesthetists (RCoA) sets the standard for unplanned admissions from day surgeries at 2%.<sup>4</sup> “True day surgeries” are defined as procedures requiring full operating theatre facilities and/or a general anaesthetic and this excludes endoscopy or local anaesthetic cases and/or procedures that can be carried out elsewhere (for example, in the community or an outpatients clinic).<sup>5</sup> Our rate of 5.5% unplanned admissions for day surgeries is above the RCoA standard but is less than some centres in the UK (10.3% at the Gateway Surgical Centre, Newham University Hospital in East London and 6.64% at the Forth Valley Royal Hospital in Larbert, Scotland).<sup>1, 6</sup>

The study also highlights the need to upgrade certain day-to-day practices. For instance, there is a definite need for better documentation by both clinicians and nursing staff. There were too many cases whose discharge was either delayed or who were admitted without any justification found in the case notes. Also, too many patients were admitted to hospital because their procedure started late in the day as is reflected in late arrivals at the PACU (stage one recovery). This may point towards the need of extending DCU opening hours beyond 1800hrs, as well as the scheduling of day cases earlier during the day. Careful planning of operating theatre lists may also help in this regard, for example, patients who are more likely to arrive late or fail to turn up may be given later slots to reduce delays during operating sessions.

A fair amount of work is already underway to facilitate the management of day cases in Mater Dei Hospital. This includes the development and implementation of clinical guidelines on the management of postoperative nausea, vomiting and pain and the piloting of a nursing checklist prior to patient discharge.

Other recommendations include the design of an enhanced recovery programme specific for day case surgeries. This would include pre-operative assessment in close collaboration with anaesthetists, the introduction of measures that minimize perioperative stressors (such as carefully titrated fluid therapy and strict maintenance of normothermia), early postoperative mobilization and physiotherapy and the prompt management of acute pain by experienced staff.<sup>7</sup> Also, the ring-fencing of beds to be used for day case procedures only may be beneficial to the running of the DCU, although one understands that this may be difficult in times when demand for acute hospital beds is high. Both may be challenging undertakings but will improve care for day case patients.

The main limitations of the study include the standard of documentation in the patients’ files and time period over which it was carried out. Data collection relied heavily on the patients’ notes, and since in some cases documentation was incomplete or difficult to interpret, results may be flawed too. Also, the study was done over a relatively short period of time which may not be truly representative of the workings of the DCU throughout the whole year. Data was collected only over a six week period but similar studies were carried over longer a span of time.<sup>1, 6</sup>

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# GPs and End of Life Decisions: Views and Experiences

Jurgen Abela

## Abstract

**Background:** The views and experiences of GPs with respect to end of life (EoL) care are seldom addressed.

**Aim:** To better understand this aspect of care.

**Design and setting:** A cross-sectional survey of all doctors in the country.

**Method:** A validated questionnaire; subgroup analysis of GPs.

**Results:** The overall response was 396 (39.7%), 160 of which were GPs. 28.7% of GPs received no formal training in palliative medicine. 89.8% of respondents declared that their religion was important in EoL care. 45.3% agreed with the right of a patient to decide whether or not to hasten the EoL. 70.5% agreed that physicians should aim to preserve life.

15% of GPs withdrew or withheld treatment in the care of these patients. 41.1% had intensified analgesia at EoL. 7.5% had sedated patients at EoL. Lastly, 89.1% GPs would never consider euthanasia.

Significant correlation ( $p < 0.05$ ) was observed between considering euthanasia, using sedation, importance of religion and patients' rights in EoL. A thematic analysis of comments highlighted the importance of the topic and feeling uncomfortable in EoL care.

**Conclusions:** There needs to be more training in palliative care. GPs believe in preserving life, would not consider euthanasia but do not shun intensification of analgesia at the end of life. There might be some misunderstanding with respect to the role of sedation at the EoL. GPs need legal and moral guidance in EoL care, in the absence of which, their religion is used as a guide.

## Keywords

End of life Care; Terminal Care; Family Medicine; Palliative Care

## Introduction

Family medicine is defined as the medical specialty, which, irrespective of the health care setting in which it functions, includes the six core competencies of primary care management, person-centred approach, specific problem solving skills, community orientation, comprehensive approach and holistic care.<sup>1</sup>

Palliative Care (PC) aims to improve the quality of life of the patient with a limited prognosis through a combined approach addressing the physical, psychosocial and spiritual nature aspects of the patient, including bereavement support to the relatives of the patient.<sup>2</sup> Historically, PC was born out of oncology. Following on a landmark study, PC has expanded to include non-cancer diseases such as heart failure and respiratory failure.<sup>3</sup> From a philosophical perspective, there is a lot of overlap between the approach adopted in family medicine and palliative care. Further to this, the RCGP EoL strategy (pg.5) states that:

Caring for people nearing the end of their lives is part of the core business of general practice. The GP and the primary care team occupy a central role in the delivery of end of life care in the community.<sup>4</sup>

More than 90% of the last year of life of PC patients is spent at home and they are cared for by generalists.<sup>5</sup> The recently launched Prague Charter exhorts governments to relieve suffering and ensure the right to proper palliative care, including the community.<sup>6</sup> Consequently, almost every family doctor will interact with dying patients at some point and identifying the goals of care can be a challenge. A particularly challenging moment is the EoL, due to the fact that ethical issues commonly arise with respect to symptom control and the management of the dying process. In fact, the ethical challenges of EoL in family medicine are reflected in a variety of documents.<sup>7</sup>

Malta is a small country with an estimated population of 420,000. It has strong traditional roots, which recently have been challenged with the introduction of a variety of civil rights, including the introduction of divorce in 2011 and the introduction of civil unions and adoptions by gay couples in 2014.

Given all of these rapid socio-cultural developments and legislations locally, the need to study

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a rather ‘controversial’ area was felt, particularly to inform any future nationwide discussion on the topic which might occur in the country. One such ‘controversial’ area is EoL care which includes decisions on withdrawing or withholding treatment, sedation and euthanasia.

## Method

The aim of the study was to quantify the thoughts amongst medical practitioners on EoL decision making. Hence a primarily quantitative methodology was adopted and accordingly, a questionnaire was used. The questionnaire was previously used in similar populations i.e. doctors and previously validated as part of the EURELD (European end-of-life consortium) initiative.<sup>8</sup> The necessary permissions were sought.

The questionnaire was sent by post to all medical practitioners who were listed on the Principal Register of the Medical Council of Malta as on November 2013. Only doctors who had a local address listed on the register were included ( $N=1007$ ). The present study is concerned with a sub-group analysis of all respondents who replied to the questionnaire and who identified their primary area of work as being family medicine.

The questionnaire consisted of four sections, followed by a short comments section. The four sections related to demographic details; details on religion/philosophy of life; thoughts on palliative care and training; and lastly a section on past experiences and views in relation to end of life decisions.

Each questionnaire had a short note included where the aims of the study were explained and consent sought. The participants were asked to fill in the questionnaire and return it back by not more than one month.

Every effort has been made to ensure a good response rate.<sup>9-10</sup> The introductory note was personalized, each participant had a prepaid envelope to return the questionnaire and the questionnaire was not long. However, contrary to existing recommendations, no reminder note was sent to the doctors. This was done since the author felt that the area being studied was ‘sensitive’ and consequently felt that a reminder was inappropriate.

The University of Malta Research Ethics Committee approved the study. The data collected was analyzed using SPSS version 22.0 and Excel version 12.3.6.

## Results

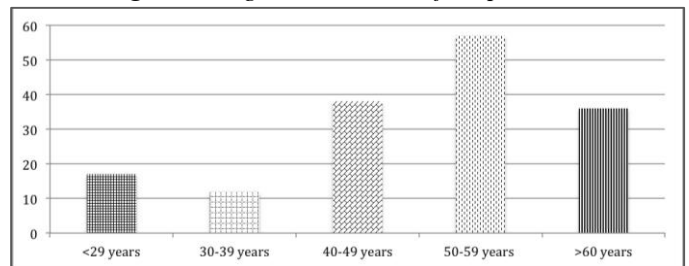
396 doctors returned their questionnaire, giving a response rate of 39.7%. Of these, 356 were actively practicing doctors (40 doctors were no longer actively practicing). Out of the total practicing doctors, 160 practiced in family medicine. The results hereunder refer to the latter sub-population of the total respondents. Section A-E refer to the quantitative results whereas the

final section presents the qualitative aspect of the study.

### A. Demographic details

Of the respondents, 113 (70.6%) were males, whereas 47 (29.4%) were females. Overall, the respondents had been practicing for an average 23.76 years (95% CI: 21.68 – 25.84). The age distribution of the respondent is shown below in Figure 1.

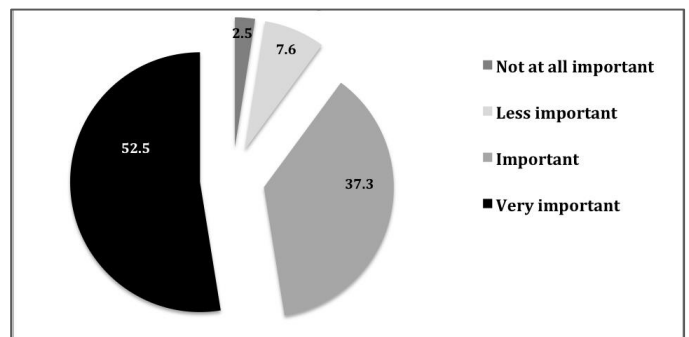
**Figure 1:** Age distribution of respondents



### B. Respondents and their religion

132 GPs (82.3%) identified the Roman Catholic Church as their religion. Further to this response, the doctors were asked to rate how important was their religion/philosophy in taking EoL decisions. The results are reproduced in figure 2.

**Figure 2:** How important is your religion/philosophy of life in making EoL decisions?



### C. Views of respondents on palliative care and EoL care

The respondents were asked to rate on a 5-point scale whether they disagree/agree with a set of statements. The results for these questions are summarized in Table 1.

### D. Training in Palliative Care

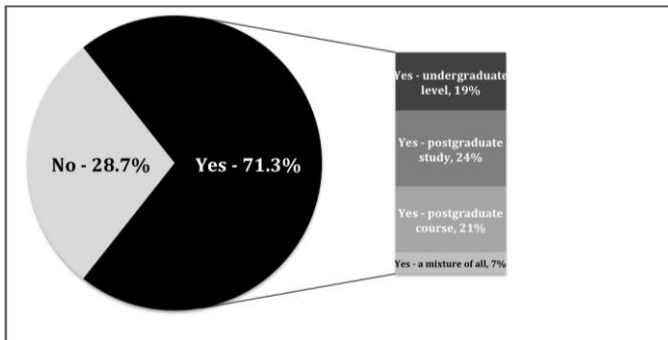
The respondents were asked about their training in palliative care. They were also asked if they agreed that training in palliative care should be increased/extended; and if so at what level – undergraduate, postgraduate education; postgraduate course or any combination. 46 GPs (28.7%) of GPs received no form of training in palliative care and 63 GPs (39.6%) do not agree to extend training in palliative care. A detailed breakdown

of responses is shown in figures 3 & 4.

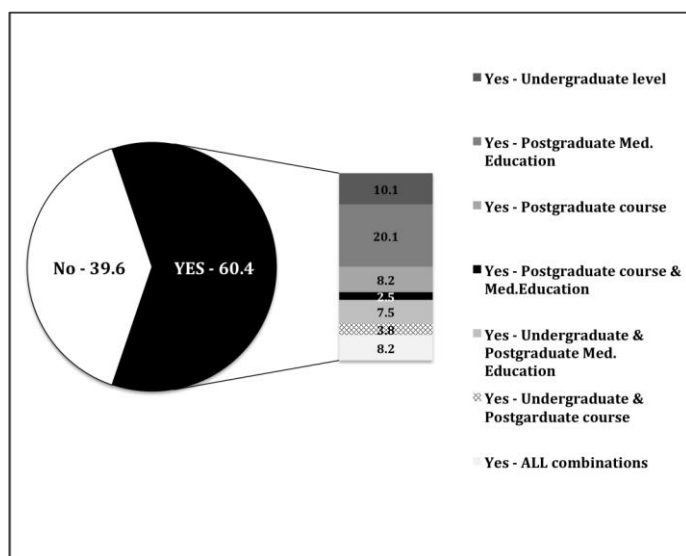
**Table 1: Questions on EoL care decisions and Palliative Care**  
( $p < 0.001$ )

Questions	Strongly Agree (%)	Agree (%)	Neutral (%)	Disagree (%)	Strongly Disagree (%)
A person should have the right to decide whether to hasten his EoL or not	1.9	43.4	31.4	12.6	10.7
Sufficient availability of high quality palliative care removes almost all requests for euthanasia in EoL	11.9	40	18.1	18.8	11.3
Physicians should always aim to preserve the life of their patients	25.8	44.7	11.9	16.4	1.3
Allowing use of drugs in lethal doses on request of patients will gradually lead to increase in the use of drugs without request by patients	20	28.1	19.4	26.9	5.6
Allowing the use of drugs in lethal doses on request by patients will harm the relationship between doctor and patient	15.6	32.5	18.8	25.6	7.5

**Figure 3: GPs and training received in palliative care**



**Figure 4: Do you agree with extending training in PC for GPs?**



## E. Situations of EoL care

Respondents were asked how many terminal patients they cared for in the last 12 months. The mean answer was 4.44 patients (95% CI: 3.67-5.21) with 35 (21.9%) stating that they did not care for a dying patient in the past 12 months.

They were subsequently asked on whether they ever withdrew or withheld any treatment to their patients. Of all the GPs, 24 (15%) had withdrew/withheld treatment. Of these:

- 13 (8.1%) had withheld treatment,
- 3 (1.9%) had withdrew treatment and
- 8 (5%) withheld and withdrew treatment.

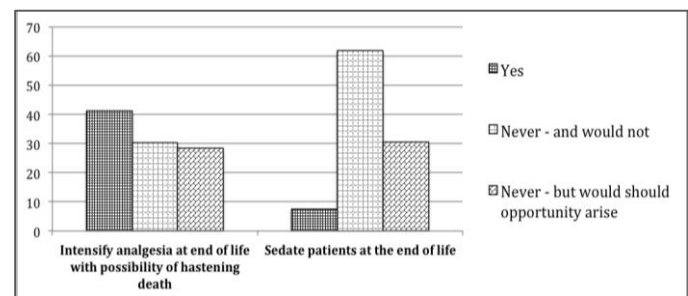
For the 136 (85%) GPs who never carried out such practices:

- 28 (17.5%) of doctors would withhold treatment;
- 2 (1.3%) would withdraw treatment
- 39 (24.4%) agree to both
- 67 (41.9%) would not withdraw/withhold treatment

For the 24 GPs (15%) who had withdrew/withheld treatment, the last time they had a patient in such situation was a mean 33.1 months ago (95%CI: 4.93 – 61.25).

The respondents were also asked about their views and experience with respect to intensification of analgesia at EoL with the possibility of hastening death and sedation of patients at the EoL. The responses to these two questions are grouped are shown in figure 5.

**Figure 5: Respondents and their views on intensification of analgesia and sedation at EoL – percentage of total**



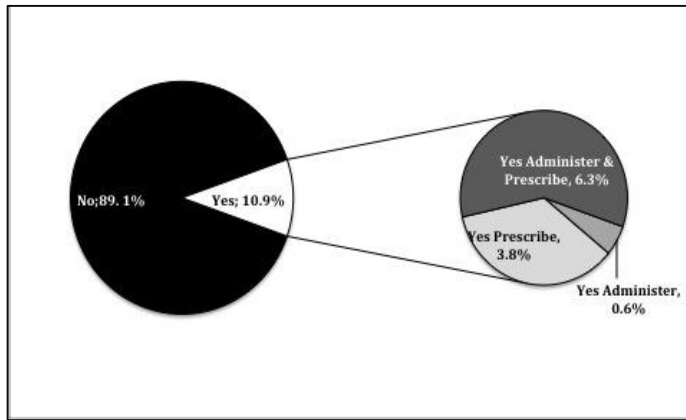
Those who responded positively to these two questions reported that they last had a patient needing intensification of analgesia 27.5 months ago (95%CI: 12.08 – 43.12), whilst with respect to sedation, the last patient they could recall was 39.27 (95%CI: 7.75 – 70.80) patients months ago.

When asked whether they ever received a request for euthanasia from patients, 23 (14.4%) answered positively, whilst 137 (85.6%) of respondents never received such requests. Of those who received a request, the last time they received a request was on average 45.15 months ago (95%CI: 13.45 – 76.85).

Finally the respondents were asked whether they

would consider euthanasia. The response is summarized in figure 6.

**Figure 6:** Would you consider euthanasia?



On further analysis, there was a significant correlation between views on considering euthanasia and views on palliative sedation ( $p=0.020$ ) and between the importance of religion and consideration of euthanasia ( $p=0.031$ ). There was also a very significant correlation ( $p<0.001$ ) between importance of religion/philosophy of life and the response to the question on the right of patients to hasten the EoL.

## F. Qualitative analysis

At the end of the questionnaire, the respondents had the option to leave comments. 77 GPs did so and a thematic analysis of their comments is presented hereunder:

### F1. Ethical and religious issues

‘According to my belief, God is the master of all living things. I have no authority to determine end of life. I cannot be Dr Jekyll and Mr Hyde (GP no.15)

‘Morally very challenging especially if there is a good relation with the patient. Cannot force doctor to do something against his moral ground’ (GP no.91)

‘Religion is paramount. God gives life and only He decides when to take it’ (GP no.281)

‘Apart from religious teachings.....primum non nocere’ (GP no. 145)

### F2. Importance of the subject

‘This subject is of extreme importance and which touches on one of the principal aims of medical practice..’ (GP no.2)

### F3. Feeling uncomfortable

‘This is one of the greatest dilemmas I could possibly face...it is also true that reassuring a patient of a dignified death reduced the request for

euthanasia. I still do not feel comfortable in any way to help anyone hasten his death’ (GP no.24)

‘Always very difficult to be ABSOLUTELY right’ (GP no. 243)

‘The most common scenario is that the patient does not know he is terminal’ (GP no. 368)

### F4. Ripple effect

‘In general people do not agree with euthanasia because of fear it will be abused. But every invention in human history - fire knife etc - has been misused. Nothing is black or white’ (GP no.76)

### F5. Legal aspects

‘If legal I would do it’ (GP no. 122)

‘Illegal in Malta’ (GP no. 274)

### F6. Symptom Control & Service Provision

‘Difference between hastening death and prolonging status quo’ (GP no. 139)

‘Distinguish between withholding; Stopping Rx to accelerate death; actively end life. Legal input especially if patient is unconscious. Problems with finding a bed where patients can die, when home is not an option’ (GP no.257)

## Discussion

### Strengths and Limitations

This was a study that explored a topic rarely studied. The response rate for the questionnaire was low. In fact, the average response rate by doctors for surveys published in medical journals is 54%.<sup>11</sup> It can be argued that the decision not to send a reminder could have possibly affected the response.<sup>12</sup> Having said this, in a past local study concerning euthanasia – and which unlike the present study included a reminder - there was a response rate of 39.3%, very similar to this study.<sup>13</sup> Consequently, the low response rate seems to be more reflective of the attitude towards questionnaires in Mediterranean countries – as opposed to northern countries - given that in original study carried out across different countries in Europe, Italy returned a response of 39%.<sup>8</sup>

The tool used – a postal based questionnaire - was informed by the conclusions of a review of physicians’ responses to questionnaires.<sup>9</sup> Thus it was a short and easy to fill in questionnaire with simple and clear instructions. No questionnaires were lost throughout the compilation of data. The use of a semi-qualitative section allowed for some themes to emerge, which could not have been identified from a purely quantitative perspective. Finally, the fact that this study concerned all doctors in the country further strengthens its findings.

### ***Comparison with existing literature & Implications for Practice and research***

89.8% of respondents consider their respective religion/philosophy of life as being important or very important in guiding their end of life decisions. Locally and internationally, in line with a secular trend in various aspects of society, it is occasionally suggested that religious guidance should be separated from medical care in end of life strategy and care as well as in a variety of other issues. It can be argued that the results of this study would suggest that such separation might seem artificial and indeed counter-productive.

A relative majority of respondents (45.3%) agreed that patients had a right to decide whether to hasten their EoL or not. This is in line with similar surveys done abroad.<sup>14</sup> A majority of respondents (51.9%) stated that with good palliative care most requests for euthanasia can be removed. This line of thought reflects a major discussion going on at a European level about the role of palliative care.<sup>15</sup> There was a significant agreement that physicians should always aim to preserve life, with just 17.7% disagreeing with such statement. With regards to the use of high doses of drugs at EoL, there was a spread of responses with a skew towards agreement with the statements which actually mean that GPs are somewhat concerned about such practices. These issues could be explained by the fact that GPs usually have few palliative patients per year. Hence the lack of regular exposure to such situations might actually make them less confident to deal with such problems and drug doses.<sup>16</sup> Training in palliative care is quite varied around the world.<sup>17</sup> It has been previously documented that training in PC for GPs can be improved.<sup>18-19</sup> The majority of respondents stated that they had some training in PC though worryingly, 28.7% never had training in PC. Most agreed that training should be increased, in line with the conclusions of a previous local study where 40.9% of GP trainees feared managing a dying patient in the community.<sup>20</sup> The need to promote training is also in line with the recently developed Primary Palliative Toolkit.<sup>21</sup> Local initiatives like the European Certificate in Palliative Care, which is run by Hospice Malta is a step in the right direction to address this lacuna of knowledge.<sup>22</sup>

The majority of GPs (58.1%) agrees with the process of withdrawing/withholding various forms of treatment at the end of life. This response might seem to contradict the strong sense of preserving life as stated previously. It should be noted that withdrawing/withholding treatment is not necessarily done with the aim or consequence of hastening death. Indeed, few are the occasions where one might argue so. Secondly, this may also suggest that GPs can clearly identify situations where a practical and flexible approach - in which death is inevitable and overtreatment becomes an issue - is necessary. There is

a possibility that attitudes to withdrawal of treatment change according to whether the decline is mainly physical or cognitive.<sup>23</sup> However, this distinction could not be ascertained in this particular study. Comparison with a similar local study is impossible with respect to this issue, since in their study, Inganez & Savona Ventura posed a different question which specifically associated withdrawal of treatment with shortening of life, which is not always the case.<sup>13</sup>

A sense of uneasiness comes in with the two questions related to intensification of analgesia and sedation at EoL in line with the literature.<sup>10</sup> This uneasiness comes out also in the qualitative section. Whereas a good number of GPs are not against intensification of analgesia (to achieve symptom control) there was a majority against sedating patients at the end of life. Internationally, despite there being recognized pathways for palliative sedation there is still raging controversy that palliative sedation might be abused and used as a form of euthanasia.<sup>24</sup> Another possible explanation of this difference in response might be difficulty in communicating such delicate issue with patients and families. This has been documented previously in the literature.<sup>25</sup> Indeed it is estimated that in the cancer setting, only 7.8% of patients discuss difficult EoL with physicians.<sup>26</sup> In the non-cancer setting this is lower due to prognostic uncertainty.<sup>27</sup> In the community setting, communication is much more challenging than in a secondary care setting since the actual care of the (moribund) patient is usually provided by the family carers. Hence the family has more leverage and possibly need more convincing. Thirdly, in Maltese - like in the English language - a commonly used phrase in veterinary medicine is 'putting an animal to sleep'. Hence sedation in patients might be associated with 'killing' even due to a linguistic issue.

Finally, 14.4% of GPs received requests for euthanasia which is significantly lower than the previously reported 25.9%.<sup>13</sup> A possible explanation could be the fact that patients are increasingly dying at hospital (despite spending most of the last year of life at home) and hence such requests are usually made during the final phases.

GPs are clearly against euthanasia and would not consider it. Considering that in the study by Inganez and Savona Ventura the percentage of GPs against euthanasia was 83.7%, it could be argued that there is an increase in GPs against euthanasia over time.<sup>13</sup> Overseas, the situation is not very much different - in a recent poll organized by the Royal College of Physicians, 82.3% of palliative care physicians were against measures to facilitate hastening death (Dr C. Gannon, Medical Director Princess Alice Hospice - personal communication).

In the qualitative section one can observe the religious beliefs/philosophy of life of GPs as being

important in guiding them in their actions, possibly due to the legal/moral vacuum in this field on a local level. In fact, as far as is known, there is no guidance from the Medical Council of Malta in this important topic.

## Conclusion

This study was about end of life decisions by GPs. It shows that most GPs are against euthanasia. There is a practical approach to end of life, where a good number of GPs would consider withdrawing or withholding treatment. GPs believe in preserving life as a guiding principle at the end of life, but do not shun intensification of analgesia at the EoL. There might be some misunderstanding with respect to the role of sedation at the end of life. GPs need guidance – legal and moral - on this subject, in the absence of which, their religion and philosophy of life is used to guide them in this rather difficult area of practice.

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# Consanguinity in the Maltese Islands

H.V.Wyatt

## Abstract

Consanguineous marriages may increase the risk of some medical conditions and may be useful to examine social and other aspects. There were few such marriages in the Maltese islands until late in the 19<sup>th</sup> C when they increased until they began to decline in the new century. These marriages were twice as common in Gozo as in Malta, but the proportion varied in parishes. In some parishes, such marriages were mainly among a few related families; some families had many consanguinities over several generations. These marriages probably reflected the social standing of the families and the lack of mixing of young people with others of lower status. Families of polio cases showed many consanguineous marriages.

## Introduction

Malta and Gozo are small islands in the middle of the Mediterranean. Almost all Maltese were Roman Catholic, with records of baptisms, marriages and deaths going back to the 16<sup>th</sup> century. The surnames are distinct with some relatively common. There is a good medical school, many of whose graduates gained qualifications and experience in Britain and the British army. It is therefore an ideal community for studying health and disease. In this paper I examine different aspects of consanguineous marriages, comparing the proportions in the two islands, in different villages, generations and date as well as between parents and grandparents of polio children and controls. Consanguineous marriages may carry possible health consequences and may also suggest social and other aspects. For families of polio cases, there were many consanguineous marriages in more than one generation.

## Keywords

consanguinity, genetic susceptibility, Malta, poliomyelitis, social status.

## Methods

With the approval of the Archbishop of Malta, the Bishop of Gozo and the Chief Government Medical Officer, I found the clinical notes of 1072 Maltese children who had been paralysed with polio between 1909 and 1964. I traced these children and their baptism matched controls (prefixed 'C') to their great grandparents. Baptisms and marriages were found in the parish registers. Where there was no trace of a marriage, the births or marriage of the parents were traced in the Public Registry and checked in the relevant parish. This study was confined to Maltese, but all marriages with foreigners were traced to a record of birth outside Malta: from the 1850's some British married Maltese. There were flourishing Maltese communities in many Mediterranean countries: Maltese who were born or married abroad were traced by searching Maltese records for their parents, writing to the kappillan in for example Tripoli or in two cases by consulting parents on holiday from Australia and America. All records of the Maltese community in Egypt were destroyed in the Suez war of 1956.

Parish registers of baptisms and marriages were consulted, but many give no details: all but one have indexes, but many documents and indexes are in appalling condition. A few give considerable detail, including, for baptisms, marginal notes of subsequent marriage. Some marriages were not entered in the parish register, some names have been transposed and the handwriting of some kappillans cannot be deciphered in either certificate or parish register. Some births, especially from the central hospital in Floriana, were illegitimate with no record of a father's name. The marriage registers record dispensations for consanguinity, eg II, III/IV etc. The two Curias have dispensation documents, but detailed analysis would require considerable effort. Because there were big disparities in adjacent years in the number of marriages, (for Malta 1058 and 846, 1436 and 1839, 1404 and 1982) and in dispensations for consanguinity (for Gozo, 3 and 19, 18 and 33), I have used averages of each.

The Public Registry started in 1863, but the early records were incomplete. In Gozo, the annual indexes and originals are easily consulted. In Malta, there were heavy annual indexes with separate compilations for common surnames and card indexes with basic information for births, and marriages from 1900, but the original certificates could not be consulted. When this study was nearly completed, card indexes for all births were ready and with reshelving of the original

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certificates consultation was possible, but not easy: some originals and index pages are missing or damaged. Records have now been transferred to computer databases.

In a few cases, the parish record was incorrect or absent, probably because the kappillan made the entries some time after the ceremony - and the celebrations. It is possible that in some villages, the priest because he was new, or through pressure or the poverty of the marriage couple, overlooked relationships or did not probe too deeply.

### Dispensations for consanguinity in Malta and Gozo

In both Gozo and Malta there was a rise in the proportion of consanguineous marriages after 1870, but since the first world war, they have declined by more than a half (Table 1). During this time the proportion in Gozo has been more than twice that of Malta. The number of marriages in Gozo has risen every year since the 1930's and in Malta the number of marriages almost

doubled since the first world war. The number of marriages each year is based on those registered in the Public Registry, but registration was only made compulsory in 1975. I have found that perhaps as many as 10% were not registered before 1900 so that the rates for consanguinity may be high. In more recent times, most marriages were recorded.

### Consanguinity in Gozo

The overall figures conceal even bigger differences between different villages. Zebbug, a small isolated village in the northwest had a high proportion of consanguineous marriages (Table 2). In contrast with this small village, there were few in the central town of Victoria. Qala, a larger village in the east with 439 adults, had fewer consanguineous marriages than Zebbug. However, surprisingly, Nadur a much larger village, had a high proportion of consanguineous marriages.

**Table 1:** *The changing pattern of dispensations for consanguinity*

Gozo	Average number each year of		
	Marriages (Public Registry)	dispensations for consanguineous	% of marriages Consanguinity
1873 – 1877	96	16	16
1883 – 1887	123	26	21
1893 – 1898	118	25	21
1914 – 1918	99	21	21
1926 – 1928 #	116	13	11
1938 – 1944 #	174	16	9
<b>Malta</b>			
1873 – 1877	812	c 50	c 6
1883 – 1887	957	c 50	c 5
1909 – 1913	941	84	9
1917 – 1919 #	1576	120	8
1927 – 1929 #	1345	c 80	c 6
1939 – 1943 #	1930	c 85	c 4
1949 – 1953 #	1797	55	3

# In 1917 the Corpus Juris Canonici reduced the reporting of impediment from IV to III which would account for some reduction in the number of dispensations. The new Canonical Law of 1983 further reduced the impediment to only II.

Until 1975 registration of a marriage was not compulsory and perhaps 5% or more were not registered: no allowance has been made for this.

Marriages were taken from the Public Registry and dispensations from the Curias at Victoria (Gozo) and Floriana, Malta. Dispensations were granted for *consanguinity*, *affinitas* and *criminale*. For years when there was no separation of dispensations for consanguinity, I have deducted estimated numbers of *affinitas* and *criminale*.

**Table 2:** Different proportions of consanguineous marriages in some villages in Gozo (details of polios and controls from the parish registers)

Parish	Adults #	Parents			Grand-parents	Grand-parents consanguineous	
		No.	No.	%		No.	%
Zebbug	275	16	3	19	32	12	38
Nadur	1045	51	13	26	114	33	29
Qala	439	13	2	15	28	11	39
		-----	-----		-----	-----	
total		80	18	23	174	56	32
Victoria	1901	51	4	8	123	7	6

# number of adults 20 to 49 years, census of 1901.<sup>1</sup>

**Table 3:** Different proportions of consanguineous marriages in some villages in Malta (from the parish records of marriages)

Parish	Adults #	Period	Marriages		Marriages consanguineous		Consanguinities
			No.		No.	%	
Gharghur	509	1881-1891	74		15	20	2 x III, 3 x III/IV, 10 x IV
Kirkop	240	1898-1917	70		13	19	II, 5 x III, III/IV, 6 x IV
Qrendi	469	1890-1895	100		17 *	17	5x II, II/III, III, 3x III/IV, 8x IV
Safi	140	1890-1895	40		6	15	II, II/III, 3 x III, IV
Gudja	387	1890-1895	100		12	12	3x II, 2x II/III, 2x III, 3x III/IV, 2xIV
Mqabba	434	1896-1905	76		4	5	II/III, III, 2 x IV
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Total							10 x II, 5 x II/III, 14 x III, 10 x III/IV, 29 x IV
Birkirkara	3200	1900	100		7	7	2 x II, 2 x III/IV, 3 x IV

# 20 – 49 yr, Census 1901<sup>1</sup> and 1932<sup>2</sup>

\* of which 2 were double consanguinities (there were also 3 *affinitas* dispensations)



**Table 4:** Families with multiple consanguinities

Parish	Child	Parent	Grand-parent 1	Grand-parent 2
A	1244	III	II/III	
	C 483	III	IV	
B	1241	II		IV
	C 484		II	IV
C	1228	III	III/IV	IV (+ <i>affinitas</i> )
	C 257	II	III	III/IV #
	1220	III	II + IV +	II/III + III
	C 1268	III	II + IV +	
	1227		III	IV
	1222		II	III/IV
	C 690	II+III	II	
	C 474	III		IV+IV
	C 1222	III	IV + III	III/IV + III/IV
	<b>C 1223</b>	<b>III</b>	<b>III/IV + IV</b>	<b>II + III/IV</b>
	<b>1223</b>		<b>IV + IV</b>	<b>III</b>
D	<b>1248</b>	<b>II</b>	<b>III</b>	<b>III</b>
E	1204	III	IV	
	1203		IV	IV
F	C 1264	III		III
G/H	1252	III		II/III
J	989	III	II + III	
K	C 225	III	III + III/IV	
	723	III	II/III + III/IV	
L	771	II + II	IV	IV

**Consanguinity in Malta**

Malta has about ten times as many people as Gozo, with larger towns such as Valletta, Floriana and the Three Towns across Grand Harbour. Mgarr, a small village in the north (not to be confused with the small port of the

same name on Gozo) is very isolated. Villages are not homogeneous and may consist of several almost separate groups. In the south east of the island around a larger, more central village of Zurrieq there is an isolated group of villages, Kirkop, Safi, Mqabba and Qrendi which might be similar to ones on Gozo. There were 70 marriages between 1898 and 1917 in Kirkop, the village of Hal-Farrug studied by Boissevain<sup>3</sup>. These small villages and Gharghur a village in the north-east showed 14.5% of consanguineous marriages compared with the 7 % of the large cosmopolitan village of B'Kara (Table 3).

A dispensation could be obtained for the marriage of uncle and niece, I/II and seven such marriages were found: three of parents of polios and two each for grand-parents of polios and controls. There were few consanguineous marriages in Valletta, but in the two parishes of St. Dominic and St. Paul Navifraga, of 49 polios, two of the parent's marriages were I/II (of which one was of also cousins, II) and of the 125 grand-parents, one was II. Among 45 controls, one parental marriage was consanguineous and of 144 marriages of grand-parents, three were consanguineous of which one was I/II.

**Multiple consanguinities in families**

There were families with multiple consanguinities (Table 4) although in village C there were many families, most of whom were related in a large complex, many of them with polio cases. The control children were closely related to families with polio cases and had probably received immunity when protected by maternal antibodies. It is probable that consanguinity had increased the probability of inheriting susceptibility to poliomyelitis. In that village one great grand-parent of polio 1228 had 4 sons and 4 daughters of whom 5 had consanguineous marriages, 3 x III and 2 x IV. Other families were not investigated.

**Discussion**

The pattern of consanguinity in Malta is fairly similar to that of inland Sardinia and the diocese of Reggio Emilia where there were very few dispensations until the late 19<sup>th</sup> C<sup>3</sup>, although the reasons for the increase and then decrease may be different.

Boissevain, a cultural anthropologist, lived in the small village of Kirkop and wrote about life in 1960 and 1961.<sup>4</sup> He gave several reasons for consanguineous marriages. Families with the highest prestige in the village could not marry social inferiors. Marriages between first cousins could keep property of grand-parents intact. Finally, cousin marriages occur because first cousins could wander in and out of each other's houses with considerable social contact and become better acquainted than unrelated persons who were

chaperoned at that time. Cousins marry because they like each other and know each other better than others. All these reasons may have applied to the family of one case with motor neurone disease which I studied. The parents' marriage was II/III plus III/IV and the marriage of the mother's parents was III.

Boissevain analysed these and other factors in his two books on Malta.<sup>4,5</sup> In his analysis of a single family, there were two first cousin marriages. The high proportion of marriages of third cousins (IV degree) in the villages is probably a legacy of the few available families when the villages were smaller and more isolated in the early nineteenth century (Table 1).

Cavalli-Sforza, Moroni and Zei<sup>3</sup> listed the chief justifications for dispensations by the Holy See of which the absolute cause is the small size of the community ie when the village has fewer than 1500 inhabitants (300 families). In their survey of marriages 1851-1950 in 74 parishes in the Parma Valley in N. Italy with fewer people than this in 1951 (page 96), many parishes, 33, had fewer than 8 % consanguineous marriages and only 9 had more than 20% of which 2 had 33% and 1 of 42%. Many of these 44 villages had fewer than 500 inhabitants in 1951. Altitude, up to 1000 metres, was a better predictor of consanguinity than the numbers of inhabitants per parish or population density. A map of the region<sup>7</sup> showed that Rigoso 22%, Bosco 11%, Piandetto 26% were at the heads of valleys and the most isolated where the next and neighbouring parish would be lower in the valley. Much of Malta and Gozo is flat and with few hills so that isolation must be the major factor. Unlike the mountains of Italy, the aerial map of Malta shows many isolated scattered houses over the south and eastern part of Malta, but few in the more hilly and rocky west and north of the island. It may be that consanguinity was higher among the more isolated houses rather than in the villages themselves. Where marriages from two villages were made, the couple might have been near neighbours on the outskirts of the two parishes. Villages on a coast have fewer neighbours and are thus more isolated although sailors and girls from the port on Gozo married in the destination port on Malta.<sup>7</sup>

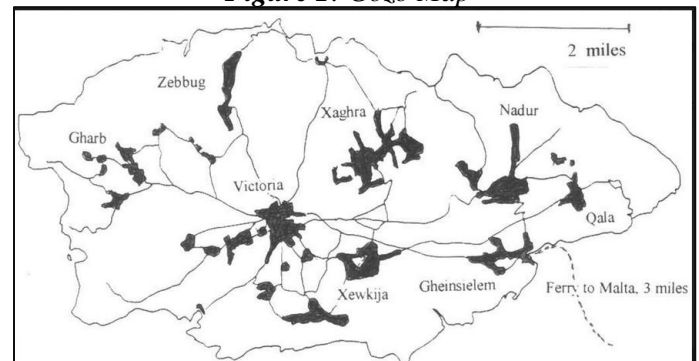
The 1901 census for Gozo<sup>1</sup> listed Ghasri, San Lawrence, Zebbug, Kercem, Sannat, Gheinseilem and Qala with fewer than 1500 persons and Xewkija with 1762 (compare with Table 1). There were, proportionately, more than twice as many consanguineous marriages in Gozo than Malta (Table 1). However, the trends were similar.

The parish registers of marriages record the consanguinities, but nothing of status or occupation, whereas certificates in the Public Registry record the occupation, where living and where born. However, the occupation is not necessarily helpful. For one family, the

parents of a polio were a double cousin (II + II) marriage, the groom was a 'farmer' and both grand-parent marriages were IV. Was the groom a high status farmer or a small-holder? The costs for a dispensation, the fees to the church and the lawyers, must have been high for poor families. The marriage of the parents of one polio was I/II + II, with the bride's parents a II consanguinity, but these were rich people. Another marriage of the parents of a polio was also a I/II consanguinity with the groom 'unemployed' but in his 60's and the bride born in Egypt. The father of another polio with a III consanguinity was a labourer. Families with a consanguineous marriage were likely to have one in a previous generation and sibs were more likely to have consanguineous marriages.

Vassallo made a study of consanguineous marriages on Malta and commented on the possible health consequences<sup>7</sup>. Vella compared the high incidence of thalassemia in Mellieha, Paula and Zebbug (Gozo) with low incidence in Floriana, Ghargur, Msida, Sliema, Naxxar and Nadur (Gozo).<sup>8</sup> However, although he gave examples of frequent intermarriage in both Mellieha and Zebbug (Gozo), Zebbug (Gozo) and Nadur did not differ significantly in their consanguinity rates (Table 3). Vella reported that 'Zebbug was described by a prominent educated villager as one large family' and of Mellieha 'intermarriage is frequent and of 30 or so marriages solemnised annually in the village in the last few years, not more than 5 each year have involved a partner who was not of local stock'. Macelli, Inglott and Sammut said of Zebbug (Gozo), that 'intra-village marriages up to the war [1940] were 80%' and 'new households set up in the village as close to the core as possible'.<sup>9</sup> However, records in the Gozo Public Registry show that many marriages in other villages, especially Victoria, involved a person born in Zebbug.

**Figure 1: Gozo Map**



## Conclusions

In Malta, it is isolation rather than altitude that determined rates of consanguinity. Although rates of consanguinity are useful, the continuity of it in families is more meaningful and tells us more of the social and, perhaps, financial mores of the villagers. Consanguinity

in families was associated with susceptibility to poliomyelitis.<sup>10-11</sup>

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I have arranged to deposit the cards and records in the Melitensis Library of the University of Malta.

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# Guideline for Screening and Diagnosing Gestational Diabetes Mellitus

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## Abstract

Gestational diabetes mellitus (GDM) is on the rise, especially with the increase in obesity in childbearing women as well as the rising prevalence of diabetes mellitus type 2. The Maltese gestational women are of no exception especially with an established link to intra-uterine nutritional environment adverse effects as well as to genetic factors.

There is no set international screening strategy for GDM and so diagnosis differs between countries. The most common diagnostic test for GDM is by performing a 75g oral glucose tolerance test (oGTT). Most countries and organizations including the World Health Organization have adopted the International Association of Diabetes and Pregnancy Study Groups (IADPSG) criteria for diagnosing GDM.

Performing a 75g OGTT on all women at risk of GDM is expensive as well as unpleasant for the women. A combination of risk criteria including pre-pregnancy body mass index with random plasma glucose and/or fasting plasma glucose based on Maltese and Mediterranean population studies have shown to be a useful screening tool. This tool would help identify women likely to have an abnormal or normal oGTT without the need to perform an oGTT.

A screening GDM protocol is essential to pick up and manage at an early stage those that are at risk to develop GDM without the need to have an oGTT performed in every pregnant woman. This would result in better perinatal and maternal outcomes.

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## Keywords

Diabetes, Gestational, guideline, risk factors, diagnosis

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## Introduction

Gestational diabetes mellitus (GDM) is defined as either diabetes or glucose intolerance, which is initially recognized during pregnancy.<sup>1</sup>

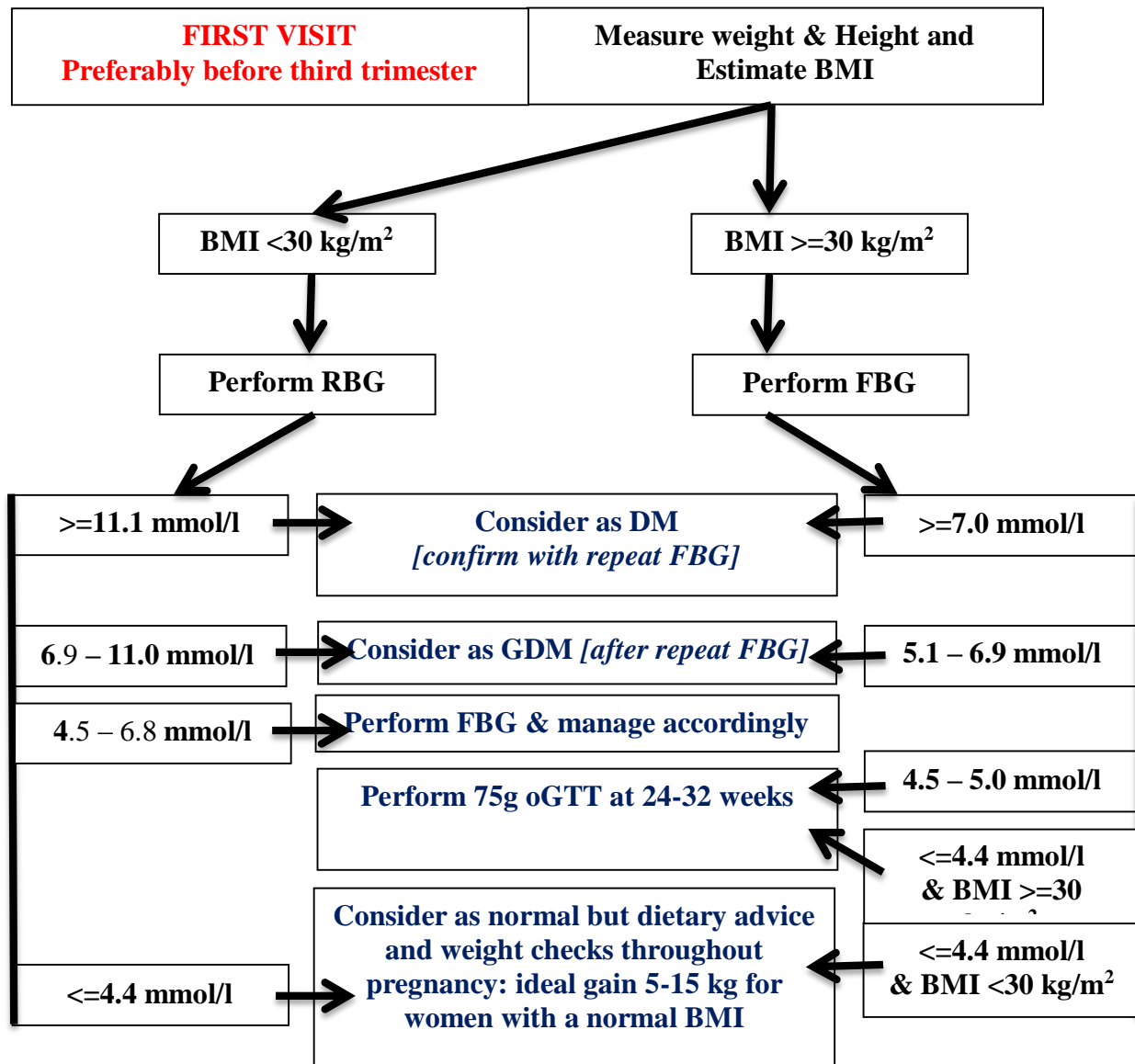
The prevalence of gestational diabetes is on the rise and has been greatly associated with the two current epidemics of type 2 diabetes mellitus and obesity in childbearing women.<sup>2</sup> Cross-sectional studies conducted on Maltese population suggested that the prevalence based on the WHO criteria was 11.5% in 1983.<sup>3-4</sup> This rate appears to have risen to 15.5% in 2010 using the same diagnostic criteria. This latter rate actually translates to 16.5% using the newly proposed IADPSG diagnostic criteria.<sup>5</sup>

The Mediterranean population has been found to be susceptible to adiposity, making pregnant women more prone to hyperglycemia and development of insulin resistance leading to GDM.<sup>5</sup> In Malta, GDM prevalence is on the rise especially with the high prevalence of obesity as well as Type 2 Diabetes mellitus.<sup>4</sup> The high prevalence of obesity and diabetes mellitus in the Maltese population have been linked to intra-uterine nutritional environment adverse effects though genetic factors may also play a part.<sup>6</sup>

## Screening for GDM

Screening for gestational diabetes has long become a common investigation performed by obstetricians during pregnancy. Using a risk based screening approach on “historic” and clinical criteria to identify risk pregnant women for GDM has been shown to be inappropriate. Studies performed on Maltese population using a risk factor screening criteria have shown a high specificity and negative predictive value with an overall moderate to low sensitivity and positive predictive value.<sup>7-8</sup>

Figure 1: Screening for diabetes during pregnancy Flow Chart



### 75gm oGTT diagnostic criteria

	Normal	GDM
Fasting:	≤5.0	≥5.1
1 hour	≤9.9	≥10.0
2 hours:	≤8.4	≥8.5 mmol/l

*Any one abnormal result  
\* pre-existing T1DM, T2DM & IGT or  
women with a past history of GDM should  
not have an oGTT repeated during*

### Diagnostic classification

**Prepregnancy DM** – known cases or elevated RBG/FBG values  
**GDM** – cases with past history of GDM, FBG >5.1 mmol/l; or two abnormal values on oGTT  
**Hyperglycaemia** – one elevated blood glucose level on oGTT at 1 hour or two hour endpoints

This was in keeping with other international studies.<sup>9-10</sup> Therefore, since using risk factor criteria is not an ideal screening tool to identify GDM women, it has been recommended that universal screening with 75g- oral glucose tolerance test (oGTT) should ideally be performed. This may not however be the most cost-effective course of management.<sup>8</sup> There is no set international screening strategy, so that screening programmes for GDM varies from one country to another.<sup>11</sup> In a Mediterranean population, the Mediterranean Group for the Study of Diabetes (MGSD) GDM study has identified that risk criteria showing a huge specificity and specificity and thus useful for screening include an elevated pre-pregnancy or third trimester maternal BMI (>25 and >30 kg/m<sup>2</sup> respectively), a maternal age greater than 30 years, and a fasting plasma glucose [FBG]  $\geq 5.1$  mmol/l. All other previously described risk factors were found to be unsuitable with very low sensitivity values.<sup>12</sup> An untimed plasma glucose value of >6.8 mmol/l or <4.5mmol/L may also be a useful screening tool to identify women likely to have an abnormal or normal oGTT.<sup>13</sup> A proposed screening flowchart is outlined below (Figure 1). This proposed screening programme is based on the IADSG and WHO-2013 proposed cut-off criteria for the oGTT in pregnancy<sup>1,14</sup> supplemented by the MGSD epidemiological studies related to GDM<sup>12</sup> and studies relating to the use of random plasma glucose [RBG] screening in the Maltese population.<sup>13</sup> An arbitrary RBG cut-off point of >6.0 mmol/l has been adopted to reduce the number of patients being inconvenienced by being recalled for an FBG.

### Diagnostic criteria for GDM

As there is no set international screening strategy, likewise the criteria used to diagnose GDM and the interpretation of the 75g oGTT varies from one country to another.<sup>11</sup>

The most common GDM diagnostic test to be performed is the oral glucose tolerance test (oGTT), usually performed during the 24 – 28 weeks of gestation.<sup>15</sup> If the mother is considered to be at a high risk to develop GDM, this test may be done much earlier in her pregnancy. Stratification whether the mother is at high risk or not, comes from the first antenatal visit to the obstetrician, where a detailed medical, family and past obstetric history and a physical examination would be performed.<sup>17</sup> A fasting or untimed plasma glucose with or without a glycosated haemoglobin estimation may also be performed to identify early pre-pregnancy undiagnosed diabetic women.

Over the years, different oGTT approaches and thresholds had been established. The 2-step approach takes its origin back to the 1964 O' Sullivan et al. study which has been adapted over the years by different

groups accordingly.<sup>18</sup> This was subsequently adopted and modified by the American Diabetes Association (ADA).<sup>19</sup> Many of the cut-off levels used to define GDM were based on 95% centile values of plasma glucose measures during an oGTT. The HAPO study carried out by the International Association of Diabetes and Pregnancy Study Groups (IADPSG) identified the cut-off criteria by looking at neonatal outcome by glucose values.<sup>20</sup> Similar observations have been made in a Mediterranean population. The World Health Organization has now adopted the IADPSG criteria.<sup>14</sup>

### Conclusions

Screening for GDM is essential since the management of these women has been shown to result in better perinatal and maternal outcomes. Two large randomized interventional trials have confirmed that intervention may reduce the risk for developing fetal overgrowth, shoulder dystocia, hypertensive disorders and caesarean delivery was established.<sup>21-22</sup>

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# Reproductive issues in the Torah

Charles Savona Ventura

## Abstract

Fertility was the basis of primitive man's economy. It is therefore not surprising to find that various facets of fertility and reproduction are mentioned and commented upon in connection to religious based texts from the period. The stories related to fertility and reproduction in these religious text compliment comments from other contemporary texts and archaeology to give an indication of the prevalent thoughts and beliefs of that age. The Torah serves as a compilation of Jewish historical religious oriented folk-tales predating the Iron Age. Its stories reflect the developing relationship and increasing dependence for survival between the Jewish people and Yahweh – a dependence inherently linked to fertility of the settled land to provide sustenance and of the people to provide for an increase in the population and communal strength.

## Keywords

Fertility, reproduction, birth, Torah, Jewish, Egyptian,

## Introduction

The Torah [Hebrew: תּוֹרָה], meaning instruction, is a compendium of Judaism's founding legal and ethical religious texts written during the Babylonian exile circa 600 BCE and completed during the Persian period circa 400 BCE. The Torah consists of the first five books of the Jewish biblical canon and has been adopted by Christianity being incorporated as part of the Old Testament. Known as the Pentateuch, the books include: the Bereshit – Genesis; Shemot – Exodus; Vayikra – Leviticus; Bamidbar – Numbers; and Devarim – Deuteronomy. The Torah is written in the form of a narrative starting with the creation of the world, the early history of the people of Israel, their Egyptian sojourn, the Egyptian exodus and the giving of the law at Mount Sinai, and ending with the death of Moses just before the people of Israel reach the promised land. The Torah thus recounts earlier historical folktales of the Hebrew [or Khabiru] population predating the Iron Age [before 1400 BCE].

The Khabiru moved in the Palestinian region as mercenaries, casual labourers or brigands from the desert margin to the east. They have often been equated with the Hebrew tribe returning through the desert from their sojourn in Egypt.<sup>1-2</sup>

The books are however not simply a historical narrative, but contain specific teachings related to religious obligations and civil laws of this community. Supplemented by the Jewish Apocrypha and later books of the Old Testament together with archaeological remains in the region, these writings have a wealth of reflections that deal with the various human lifecycles as perceived by human society at the time. These cycles include Birth-Sexuality-Death, Puberty-Fertility-Menopause, and Conception-Pregnancy-Parturition. This corpus thus reflects on fertility and its control, on concepts relating to aetiology of miscarriages and malformations, and further relate the contemporary management of labour and delivery besides describing a number of abnormal obstetric cases. These concepts can be compared and contrasted with the contemporary archaeological records and medical papyri found in the adjoining land of Egypt. The Ancient Egyptians with their belief in the afterlife left detailed representations of their way of life in the various contemporary inscriptions and pictograms left in their tombs and temples. Gynaecological problems and their management in Ancient Egypt are mainly documented in the *Kahun Gynaecological Papyrus*. The Kahun Papyrus, housed in the University College London, is dated to this period by a note on the recto which states the date as being the 29<sup>th</sup> year of the reign of Amenemhat III (c. 1825 B.C.E.).<sup>3</sup>

## Fertility and Infertility

Fertility was a central theme of many Neolithic cultures prevalent around the Mediterranean basin. It served also as the basis of the extended family's economy. Fertility was particularly directed towards the agricultural and husbandry gifts of the so-called fertility deity that enable the survival of the community. In the Semitic mythology, the Semitic mother goddess refers to Asherah (Hebrew: אֲשֶׁרָה). It appears the Hebrews continued to worship Asherah even after their supposed adoption of monotheism, and 'the worship of Baal and Asherah persisted among the Israelites for over seven centuries, from the period after the conquest and settlement of Canaan, which most biblical scholars place at around 1400 BC, to the time of the destruction of Jerusalem by Nebuchadnezzar and the exile of the Israelites in Babylon in the 6th century BC'.<sup>4</sup> The

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abrogation of the cult of Asherah was strongly advocated in the Torah books. *Exodus* 34:13 states: 'But ye shall destroy their altars, break their images, and cut down their groves' [referring to the Asherah poles]; while *Deuteronomy* 16:21-22 states 'Thou shalt not plant thee a grove [Asherah pole] of any trees near unto the altar of the LORD thy God, which thou shalt make thee. Neither shalt thou set thee up any image; which the LORD thy God hateth.' The term 'groves' in the King James Version refers to the Asherah pole, a sacred tree or pole that stood near the Canaanite religious locations to honour Asherah.<sup>5-6</sup> Further reference to the cult of Asherah [or Ashtoreth] within Hebrew culture is made in later books of the Old Testament. King Manasseh [reign circa 687 – 643 BCE] is reported to have placed an Asherah pole in the Jewish Holy Temple at Jerusalem. *2 Kings* 21:7 states that 'he [Manasseh] set a graven image of the grove that he had made in the house, of which the LORD said to David, and to Solomon his son, In this house, and in Jerusalem, which I have chosen out of all tribes of Israel, will I put my name for ever.'<sup>7</sup> These were subsequently destroyed and removed by King Josiah [reign circa 641–609 BCE] with *2 Kings* 23:6 stating that 'he [Josiah] brought out the grove from the house of the LORD, without Jerusalem, unto the brook Kidron, and burned it at the brook Kidron, and stamped it small to powder, and cast the powder thereof upon the graves of the children of the people'.<sup>8</sup> Asherah was considered to be the deity responsibility for fertility and infertile Hebrew women may have resorted to this deity to overcome their problem. The previously infertile Rachel is known to have taken the pagan household deity images from her father's house sited in Haran and 'put them in the camel's furniture, and sat upon them. And Laban searched all the tent, but found them not'.<sup>9</sup> Haran is almost universally identified with Harran, an Assyrian city in Upper Mesopotamia whose ruins lie within present-day Turkey. The Assyrians followed the polytheistic Assyro-Babylonian religion. Their pantheon included Ishtar, equated with the Ugarit Asherah, who was the goddess of fertility, war, love, and sex.<sup>10</sup>

High fertility was thus strongly desired being viewed as an enrichment of the extended family group in both nomadic and farming societies. The birth of a child, particularly a son, was considered to be a gift from Yahweh reflecting his benevolence on the woman and family or simply in compensation. 'And God blessed them, and God said unto them, Be fruitful, and multiply, and replenish the earth, and subdue it: and have dominion over the fish of the sea, and over the fowl of the air, and over every living thing that moveth upon the earth.'<sup>11</sup> 'And Adam knew Eve his wife; and she conceived, and bare Cain, and said, I have gotten a man from the LORD.'<sup>12</sup> 'And when the LORD saw that Leah

was hated, he opened her womb...'.<sup>13</sup> Fertile women were honoured while the barren were to be pitted. Thus 'And when Rachel saw that she bare Jacob no children, Rachel envied her sister; and said unto Jacob, Give me children, or else I die.'<sup>14</sup> The Kahun Papyrus gives a number of features one should look for to assess whether the woman is fertile or infertile. These varied methods range from a simple examination of the breasts to placing an onion bulb in the vagina overnight and identifying the odour in the patient's nose the next day. One could also determine the number of children she would bear by assessing the number of times the woman vomits after being made to sit on the ground smeared with dregs of beer and given fruit [?dates].<sup>3</sup>

Very grand multiparity was however not the norm. The majority of families mentioned in the Torah had six to seven children [Japheth – 7 children; Cush – 6 children; Mizraim – 7 children; Keturah – 6 children; Milcah – 7 children; Eliphae – 7 children; Leah – 6 children]. Others had less. Only Joktan and Ismael had 13 and 14 children respectively, though the text does not define whether these were from one spouse or more. Fertility throughout a woman's reproductive life, without the facility of contraception, would have been controlled by the prolonged lactation period and delayed infant weaning common in earlier practices even though wet-nursing was apparently practiced especially in the higher social strata. Thus when the Pharaoh's daughter discovered Moses in the basket among the reeds, the first thought was of finding a wet nurse to care for the child. 'Then said his sister to Pharaoh's daughter, Shall I go and call to thee a nurse of the Hebrew women, that she may nurse the child for thee?'.<sup>15</sup> The wet nurse became an important feature of the child's eventual life accompanying the child in adulthood so that 'they sent away Rebekah their sister, and her nurse, and Abraham's servant, and his men'.<sup>16</sup>

Active forms of contraception were not generally desired or the norm. However coitus interruptus was practiced by Onan to deprive his sister-in-law Tamar the opportunity to continue his dead brother's family line, an obligation placed upon him by his father Judah. Onan was punished for his actions. Thus 'Judah said unto Onan, Go in unto thy brother's wife, and marry her, and raise up seed to thy brother. And Onan knew that the seed should not be his; and it came to pass, when he went in unto his brother's wife, that he spilled it on the ground, lest that he should give seed to his brother. And the thing which he did displeased the LORD: wherefore he slew him also.'<sup>17</sup> The importance of maintaining and propagating the family line occasionally led to drastic measures to achieve impregnation by the head of the family. Tamar eventually resorted to subterfuge to achieve a pregnancy. Disguising herself as a prostitute, she enticed her father-in-law to impregnate her to

become pregnant with twins.<sup>18</sup> Similarly Lot's daughters resorted to incest getting themselves impregnated by their father after getting him drunk to 'preserve seed of our father'.<sup>19</sup> Both daughters thus became pregnant by their father. The use of a hand-maid or slave-girl as a form of surrogacy was also resorted to. In the light of her apparent infertility, Rachel offered her spouse Jacob her maid Bilhah to serve as an alternative surrogate spouse to carry a child stating 'Behold my maid Bilhah, go in unto her; and she shall bear upon my knees that I may also have children by her'.<sup>20</sup> Similarly Sarah offered the Egyptian slave girl Hagar for the same purpose telling Abram 'Behold now, the LORD hath restrained me from bearing: I pray thee, go in unto my maid; it may be that I may obtain children by her. And Abram hearkened to the voice of Sarai'.<sup>21</sup>

Other alternative means to achieve contraception in the 2<sup>nd</sup> millennium BCE are described in the Kahun Papyrus. These include resorting to the use of a mixture of crocodile dung chopped over HsA and awyt-liquid; or sprinkling honey on the womb upon a bed of natron; or sprinkling the womb with HsA and awyt-liquid.<sup>3</sup> Other forms of contraception included male sterilization since eunuchs were apparently a feature of Jewish society described in later Old Testament books – 'Neither let the son of the stranger, that hath joined himself to the LORD, speak, saying, The LORD hath utterly separated me from his people: neither let the eunuch say, Behold, I am a dry tree. For thus saith the LORD unto the eunuchs that keep my sabbaths, and choose the things that please me, and take hold of my covenant; Even unto them will I give in mine house and within my walls a place and a name better than of sons and of daughters: I will give them an everlasting name, that shall not be cut off'.<sup>22</sup>

Infertility was considered a punishment from Yahweh who closed the wombs of women considered sterile. Thus Jacob's rejoinder to his sterile wife's plea to impregnate her was "Am I in Yahweh's stead, who hath withheld from thee the fruit of the womb?"<sup>23</sup> Rachel possibly had an obesity-related subfertility since we are told that 'Leah was tender eyed; but Rachel was beautiful and well favoured'.<sup>24</sup> In Semitic mentality, "well favoured" could very well have referred to generously endowed pelvic proportions as depicted in the pagan deity Asherah. Household infertility was also Yahweh's punishment to Abimelech who had unknowingly taken Abraham's spouse Sarah to his harem. In this episode, Yahweh is said to have closed the wombs of all women in Abimelech's household – or was this a case of self-limiting male infertility? Being the result of a misdemeanour, the curse of infertility was removed after 'Abraham prayed unto Yahweh: and Yahweh healed Abimelech, and his wife, and his maidservants; and they bore children. For the LORD had fast closed up all the wombs of the house of Abimelech,

because of Sarah Abraham's wife'.<sup>25</sup> Sarah herself was infertile, though her infertility was attributed to age-related cessation of menses since the Genesis 18:11 reports that 'Now Abraham and Sarah were old and well stricken in age; and it ceased to be with Sarah after the manner of women'.<sup>26</sup>

Phytotherapy in the form on *duda'im* was also resorted to by Rachel in the management of her infertility. 'And Reuben went in the days of wheat harvest, and found *duda'im* in the field, and brought them unto his mother Leah. Then Rachel said to Leah, Give me, I pray thee, of thy son's *duda'im*. And she said unto her, Is it a small matter that thou hast taken my husband? and wouldest thou take away my son's *duda'im* also? And Rachel said, Therefore he shall lie with thee to night for thy son's *duda'im*'.<sup>27</sup> It is difficult to botanically identify the *duda'im*, which seemingly is available at the time of the harvest. Most biblical commentators identify the plant as the mandrake based on the fact that the word *duda'im* has the same numerical value as *ke'adam* meaning 'like man'. The mandrake root resembles the human form with head, hands and feet. Because of the human shape of its root, mandrake was universally associated with fertility.<sup>28</sup> Rachel eventually conceived and normally delivered a healthy normal male infant, the conception attributed as a gift from God. 'And Yahweh remembered Rachel, and Yahweh hearkened to her, and opened her womb. And she conceived, and bare a son; and said, Yahweh hath taken away my reproach: And she called his name Joseph; and said, The LORD shall add to me another son'.<sup>29</sup> Her second pregnancy conceived spontaneously was to terminate in a complicated labour and delivery resulting in her death. The Kahun papyrus further gives a recipe to assist pregnancy: after ceases the return ..... pound, grind fine, [strain] in cloth on gruel ayt, pour mehyu ..... Incense, fresh fat, dates, sweet beer, put inside a rack (of wood) in the flame; thou shalt fumigate ..... as a sweetener of the mouth.<sup>3</sup> A diagnosis of pregnancy was made on the ability of pregnant urine to germinate cereals: 'Another test for woman who will bear or a woman who will not bear. Wheat and spelt: let the woman water them daily with her urine like dates and like sh'at seeds in two bags. If they both grow, she will bear; if the wheat grows, it will be a boy; if the spelt grows, it will be a girl. If neither grows, she will not bear'. Investigations to assess whether there is any truth in this diagnostic test have suggested that it may actually be useful to detect pregnancy but not identify the foetal gender.<sup>30</sup>

## Pregnancy and childbirth

Pregnancy is fraught with a number of complications during the antenatal period and the during the delivery process. One cause for miscarriages or early

pregnancy interruption mentioned in the Torah is physical trauma – ‘If men strive, and hurt a woman with child, so that her fruit depart from her, and yet no mischief follow: he shall be surely punished, according as the woman's husband will lay upon him; and he shall pay as the judges determine. And if any mischief follow, then thou shalt give life for life, Eye for eye, tooth for tooth, hand for hand, foot for foot, Burning for burning, wound for wound, stripe for stripe’.<sup>31</sup> The Ebers Papyrus gives an abortive remedy, using a ground mixture of the acanthus fruit, onion and dates pulverized in a vessel containing honey. The mixture is sprinkled on a cloth and applied to the vulva [or inserted into the vagina]. The Ebers Papyrus was said to have been found in the Assasif district of the Theben necropolis. It is dated by a passage on the verso to the 9<sup>th</sup> year of the reign of Amenhotep I (c. 1534 B.C.E.).<sup>32</sup>

Foetal development was seen as dependant on the male element with the womb acting a nourishing moulding receptacle for the child. This is clearly described in the Wisdom of Solomon, a later text of the Old Testament: ‘I myself also am a mortal man, like to all, and the offspring of him that was first made of the earth, And in my mother's womb was fashioned to be flesh in the time of ten months, being compacted in blood, of the seed of man, and the pleasure that came with sleep. And when I was born, I drew in the common air, and fell upon the earth, which is of like nature, and the first voice which I uttered was crying, as all others do. I was nursed in swaddling clothes, and that with cares. For there is no king that had any other beginning of birth. For all men have one entrance into life, and the like going out’. The mentioned ten months refer to the ten lunar months required for foetal development.<sup>33</sup>

Foetal development within the maternal womb was believed in the Torah to be affected by visual impressions – ‘And Jacob took him rods of green poplar, and of the hazel and chestnut tree; and pilled white strakes in them, and made the white appear which was in the rods. And he set the rods which he had pilled before the flocks in the gutters in the watering troughs when the flocks came to drink, that they should conceive when they came to drink. And the flocks conceived before the rods, and brought forth cattle ringstraked, speckled, and spotted’.<sup>34</sup> There can be no doubt that ancient like modern human society was affected with all forms of congenital anomalies. These included lethal abnormalities such as the spina bifida affecting one of the embalmed fetuses discovered in Tutankhamen's tomb in 1926.<sup>35</sup> Other abnormalities reported from various mummies included clubfoot, cleft palate, and hydrocephalus. Tolerance towards malformed individuals was taught in the Instruction of Amenemope dated to the end of the 2<sup>nd</sup> millennium BC: ‘Do not laugh at a blind man nor scorn a dwarf nor spoil the plan of a lame man. Do not scorn a

man who is the hand of god nor be fierce of countenance towards him when he has erred’.<sup>36</sup> Malformed individuals who survived were accepted in society and could advance themselves in the social hierarchy. A relief in the tomb of Mereruka at Saqqara [ca.2330 BCE] depicts dwarves involved in metallurgical works. At least another 200 depictions of dwarves are found in other tombs at Giza and Saqqara.<sup>37</sup> Some dwarves reached the pinnacle of the social strata as evidenced by the VI Dynasty limestone-painted statue depicting the achondroplastic dwarf Seneb and his normal family who was honoured with a lavish tomb in a royal cemetery close to the pyramids. Seneb was the overseer of the palace dwarves, chief of the royal wardrobe and priest of the funerary cults of Khufu. A fine statue in the Cairo Museum depicts him with his family, including his wife who was of normal stature, and two children. His wife was known to have been a lady of the court and a priestess.<sup>38</sup>

The antenatal period could be a very uncomfortable one especially when the pregnancy was a twin gestation – ‘..Rebekah his wife conceived. And the children struggled together within her; and she said, If it be so, why am I thus?’<sup>39</sup> Twin pregnancies could be monozygotic or dizygotic. The twin brothers Pharez and Zarah born to Tamar appear to have been monozygotic sharing the same amniotic cavity. During the delivery, Zarah had a prolapsed arm that was pulled back into the uterus allowing the eventual birth of his twin. – ‘And it came to pass in the time of her travail, that, behold, twins were in her womb. And it came to pass, when she travailed, that the one put out his hand: and the midwife took and bound upon his hand a scarlet thread, saying, This came out first, And it came to pass, as he drew back his hand, that, behold, his brother came out: and she said, How hast thou broken forth? this breach be upon thee: therefore his name was called Pharez. And afterward came out his brother, that had the scarlet thread upon his hand: and his name was called Zarah’.<sup>40</sup> The twin brothers Esau and Jacob were on the other hand dizygotic and non-identical twins – ‘And Jacob said to Rebekah his mother, Behold, Esau my brother is a hairy man, and I am a smooth man’.<sup>41</sup> The birth of the non-identical twin birth of Esau and Jacob to Rebekah, wife of Isaac is described in Genesis 25:24-26 – ‘And when her days to be delivered were fulfilled, behold, there were twins in her womb. And the first came out red, all over like an hairy garment; and they called his name Esau. And after that came his brother out, and his hand took hold on Esau's heel; and his name was called Jacob: and Isaac was threescore years old when she bare them’.<sup>42</sup>

Parturition as described in the Torah was managed by midwives or traditional birth attendants who used birthing stools to achieve delivery. ‘Then the king of

Egypt said to the Hebrew midwives, one of whom was named Shiph'rah and the other Pu'ah, "When you serve as midwife to the Hebrew women, and see them upon the birthstool, if it is a son, you shall kill him; but if it is a daughter, she shall live." But the midwives feared Yahweh, and did not do as the king of Egypt commanded them, but let the male children live.<sup>43</sup> Birthing stools were widespread tools throughout the eastern Mediterranean with archaeological evidence for their use being described in Egypt – e.g. relief at the Temple of Hathor at Dendera. An alternative method of delivery may have been with the woman sitting on her haunches with legs raised on bricks/stones with an assistant supporting the back. This may have the meaning of Rachel's comment relating to her maid's delivery when she states that '... she may bear upon my knees....'.<sup>20</sup> Birthing bricks have been excavated from the archaeological site at Abydos in Egypt, while a Ptolemaic Period statuette depicting a parturient woman sitting on her haunches with legs raised has been excavated from Egypt. Alternative birthing positions noted in Egyptian archaeology appears to be the squatting position as evident in the relief showing the parturient woman at Sobek Temple at Kom Ombo. Egyptian women appear to have withdrawn to birth huts outside the house for the birth and for a ritual purification period of at least two weeks. These birth huts may have been the precursors of the birth houses or mammisi annexed to Ptolemaic period temples, e.g. at Dendera, Edfu and Philae. These mammisi may have also been extant in temples from the New Kingdom such as the temples of Mut at Karnak, the temple of Luxor, and Deir el-Bahari. These birth houses served to request divine help by pregnant women rather than being a birthing place. Egyptian deities commonly associated with the protection of mother and child such as Bes and Taueret were often depicted in these houses.<sup>44</sup> Bes was depicted as a dwarf with ugly features. The appearance was meant to frighten off any spirits that might be harmful to the child. Taueret was depicted with the head of a hippopotamus, the legs and arms of a lion, the tail of a crocodile, human breasts, and a swollen belly. She was often depicted holding the Sa amulet symbolizing protection.<sup>10</sup>

The birthing process was reported to be generally smooth and quick in Hebrew women preceding the arrival of the midwife so that 'The midwives said to Pharaoh, "Because the Hebrew women are not like the Egyptian women; for they are vigorous and are delivered before the midwife comes to them."'.<sup>45</sup> Labour pains were assumed to be a punishment from Yahweh based on the comment that 'To the woman he said, "I will greatly multiply your pain in childbearing; in pain you shall bring forth children "''.<sup>46</sup> While the midwives comments to the Pharaoh suggest a generally smooth

delivery, this was not always the case. The Jewish Apocrypha test states that 'Then were the entrances of this world made narrow, full of sorrow and travail: they are but few and evil, full of perils, and very painful'.<sup>47</sup> A number of complicated deliveries are described in the Torah. The worst obstetric case scenario was the birth of Benjamin to Rachel. This was the second pregnancy of Rachel, having previously given birth without mishap to Joseph. This pregnancy was apparently spontaneous probably conceived during the undertaking an arduous journey since she was apparently menstruating in the early phase of the journey since on encountering her father, Rachel 'said to her father, "Let it not displease my lord that I cannot rise up before thee; for the custom of women is upon me"'.<sup>9</sup> The 'custom of women' generally refers to menstruation when used in the Torah books, it could also possibly refer to pregnancy in this instance. During the journey she started labour, possibly prematurely. The labour was difficult and prolonged. The foetus was presenting in the breech enabling the midwife to determine the gender prior to its delivery. Rachel passed away soon after the delivery of her son possibly as a result of postpartum haemorrhage resulting from uterine atonia following the prolonged labour.<sup>48</sup> Uterine inertia from atonia is further mentioned in a later book of the Old Testament with the statement '....for the children are come to the birth, and there is not strength to bring forth'.<sup>49</sup> Other described intrapartum problems described in the Torah is the case of prolapsed arm of the presumably monoamniotic second twin with spontaneous resolution and delivery mentioned earlier. The prognostic signs of survival of the newborn were detailed by the Ebers Papyrus: 'Another way of knowing about a child the day he is born: If he says ni, it will live. If he says ba, it will die.' Another way of knowing: 'If it let a loud lamentation be heard, it will die. If it looks down its face it will thereupon die.'<sup>32</sup>

The Torah fails to detail management options in cases of obstructed labour. According to the Ebers papyrus labours could be aided by applying peppermint to the buttocks, or pouring crushed pot of a new hennu vessel in warm oil to the genitals. Another recipe included plastering a mixture of sea salt, wheat grain and female reed onto the abdomen. A mixture of salt and honey taken orally was also supposed to help.<sup>32</sup> The Hebrew Talmud makes reference to resorting to post-mortem Caesarean section when discussing whether undertaking to perform the procedure during the Sabbath was permissible – 'Only cutting flesh? Rabbah said: It is necessary [to permit the] fetching of the knife by way of a public thoroughfare? But what is he informing us? That in case of doubt one may desecrate the Sabbath! ..... Here where it [the embryo] did not have such original presumption of life, one might say no [desecration of the Sabbath shall be permitted], therefore

we are informed [that it is]’.<sup>50</sup> Intra-uterine foetal destruction to manage obstructed labour was considered an acceptable option – ‘If a woman has difficulty in childbirth, we cut up the offspring in her womb and remove it limb by limb, because her life comes before its life. If most of it [the child] has come out, we do not touch it, because we do not push aside one life for another’.<sup>51</sup> Prolonged labour could have dire consequences leading to a maternal death as in the case of Rachel or maternal anatomical damage. The mummy of Pharaoh's Queen Henhenit dated circa 2050 BCE discovered in Thebes was found to have a vesicovaginal fistula. The mummy had an abnormally shaped pelvis with a reduced transverse diameter and a high sacral promontory. Obstructed labour probably caused her death as the baby was likely to have been delivered with force, causing the bladder tear.<sup>52</sup>

## Management of the Puerperium

The Hebrews had very strict hygienic laws that detailed the period of time the woman was considered unclean because of her lochial discharge. The duration depended on the gender of the child lasting 40 days after the birth of a son and 80 days after the birth of a daughter – ‘And the Lord spake unto Moses, saying, Speak unto the children of Israel, saying, If a woman have conceived seed, and born a man child: then she shall be unclean seven days; according to the days of the separation for her infirmity shall she be unclean. And in the eighth day the flesh of his foreskin shall be circumcised. And she shall then continue in the blood of her purifying three and thirty days; she shall touch no hallowed thing, nor come into the sanctuary, until the days of her purifying be fulfilled. But if she bore a maid child, then she shall be unclean two weeks, as in her separation: and she shall continue in the blood of her purifying threescore and six days’.<sup>53</sup> In addition, ‘if a woman have an issue of her blood many days out of the time of her separation, or if it run beyond the time of her separation; all the days of the issue of her uncleanness shall be as the days of her separation: she shall be unclean. Every bed whereon she lieth all the days of her issue shall be unto her as the bed of her separation: and whatsoever she sitteth upon shall be unclean, as the uncleanness of her separation. And whosoever toucheth those things shall be unclean, and shall wash his clothes, and bathe himself in water, and be unclean until the evening’.<sup>54</sup>

Infants were breastfed up to their third year of life, though high-ranking women and queens delegated this task to wet nurses who became an integral part of the family. The mother deity Isis herself was repeatedly depicted breastfeeding her son Horus.<sup>37</sup> The Ebers Papyrus describes the use of milk stimulant recipes including smearing the back with a mixture of ground

Nile-perch bones fried in oil. Alternatively the nursing mother ate bread made from soured durra with poppy plant.<sup>32</sup> The breastfeeding mother of course had further recourse to the deity Taueret.<sup>10</sup>

## Conclusion

The basis of the economy and thus survival in the nomadic and agricultural tribes living in the Eastern Mediterranean was highly dependent on the size of the extended family or community. Numbers ensured that the community could produce sufficient resources for its survival and ensured its safety from attack from other neighbouring communities. Children were needed to ensure the parents’ care in later life and ensure the performance of required burial rites to enable the enjoyment of everlasting life in the afterlife. It is no wonder that fertility was a highly prized “gift from the deities” who needed to be appeased and obeyed to retain their continuing benevolence.

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# Circular areas of erythema on the mid forehead

Ebtisam Elghblawi, Justine Bugeja

## Abstract

Cupping is well known as a complementary treatment and remains in use for many ailments, including dermatological conditions. We report a case who presented with a skin lesion on her forehead.

**Keywords:** cupping, complementary medicine, alternative medicine, skin.

## Introduction

Cupping is a form of complementary and alternative medicine (CAM) that is used in the Muslim world, as well as in North Africa, the Far and Middle East, Eastern Europe and Latin America. The technique involves the application of ignited alcohol-soaked cotton in a glass cup or jar. The container is then applied to the skin over the area of interest. The area of skin can either be left as is (dry cupping) or it may be scratched and otherwise incised with a sharp object, such as a knife (wet cupping).

The cup is left over the site and on cooling, generates a partial vacuum. This is said to draw “spoiled blood” and other “contaminants” as well as eliminating sluggish flow. Moreover, cupping is performed over acupuncture spots in the belief that this stimulates the body's vital energy.

## Clinical presentation

Initially presenting in view of hand eczema, a middle-aged lady was noted to have particular skin findings on her forehead. She was not concerned about the latter; she was reporting headaches and seeking complementary treatment (Figure 1). This resulted in a single, well-defined, rounded red skin lesion over the mid-forehead, with some ecchymosis at the lower edge. This resolved over a one week period with no treatment or intervention.

## Discussion

Cupping is an old modality of complementary treatment which is usually carried out by non medical individuals, such as village elders and “pious” men, who have learnt the technique from their ancestors, eventually passing it on to the next generation.

Cupping has a distinctive physical appearance: round areas of erythema which may become oedematous and ecchymotic due to capillary leak. In order to cover a larger surface area, the cup can be moved around over lubricated skin: this creates the effect of linear purpuric streaks. If the physician is not aware of this practice, these benign lesions can be mistaken for injuries seemingly inflicted through abuse.

Cupping can cause significant dermatological issues. The practice has been purported to induce Köebner phenomenon, commonly seen in cases of psoriasis<sup>1</sup>, as well as keloid formation at cupping sites<sup>2</sup>. Cupping may also exacerbate eczematous areas<sup>3</sup>, and may trigger post inflammatory hyperpigmentation<sup>4</sup>. Additionally cupping was found to lessen post-herpetic neuralgia through its influences on substance P<sup>5</sup>.

When cupping was utilized for non-specific neck and back pain, it was found to improve symptoms significantly. There is no definitive conclusion due to high dropout rates<sup>6</sup>.

In conclusion, the benefits of cupping are difficult to analyse as there are no randomized control trials which prove or disprove its efficacy.

**Figure 1:** Mid forehead rounded skin lesion



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