

The number of consultant clinical chemists in the 15-nation European Union¹⁾

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Abstract

The number of consultant clinical chemists (NCCC) in the 15-nation European Union (EU) (Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, The Netherlands, Portugal, Spain, Sweden, United Kingdom) has been ascertained. These data were analysed in relation to several established national parameters, including demographics, gross domestic product (GDP), cost of healthcare, cost of in vitro diagnostic (IVD) testing and the number of physicians and pharmacists. Large differences in the population-corrected costs of IVD testing (range ~2.4-fold) and NCCC (range ~30-fold) were observed between the countries, which could not be satisfactorily explained by any of the parameters assessed. The differences in IVD testing and NCCC might reflect different practices in laboratory medicine across the EU, but could not be estimated independently. In recognition of the different scope of laboratory medicine practised under the title of clinical chemistry, a simple staffing model was derived in an attempt to give a better estimate of the appropriate number of consultant laboratory medicine specialists. This model allocated a fixed number of laboratory specialists per million inhabitants for the five disciplines: clinical chemistry, 10; haematology, 10; serology, 7.5; microbiology, 12.5; and blood banking, 2. The staffing model also allowed for the contribution of the primary care sector by including one full-time consultant laboratory medicine specialist for each small private laboratory and two extra consultant laboratory specialists per million inhabitants where there are not

large numbers of private laboratories. Application of the model to the available data helped to reduce the variation observed in the primary analysis of NCCC (range ~9-fold) but still revealed important differences between countries. These differences could arise from the poor quality of published data as much as from true differences in laboratory medicine practice. We conclude that a more sophisticated analysis of laboratory practice and of all professionals working in laboratory medicine disciplines would be required before any conclusions could be drawn about relative staffing, efficiency or cost effectiveness. The staffing model derived is a first step towards objective estimation of the number of consultant laboratory specialists in the EU.

Keywords: consultant clinical chemists; European Union; laboratory medicine; population demographics; staffing model.

Introduction

For many years the EU national societies of clinical chemistry and laboratory medicine have worked together in the European Communities Confederation of Clinical Chemistry and Laboratory Medicine (EC4) (1). In an attempt to understand better the practice of clinical chemistry within the EU, the Executive Board of EC4 established a Working Group to ascertain the number of consultant clinical chemists (NCCC) across the established 15 nations of the EU and to analyse these data in relation to a range of national parameters. The rationale for the study was that, with development and expansion of the EU, political initiatives are likely to include projects to compare healthcare regulations, procedures and practice with a view to greater harmonisation. EC4 believed that its study could provide useful background information to enable it and national societies of clinical chemistry and laboratory medicine to contribute to such projects.

There is surprisingly little information in the literature on the NCCC in Europe. This comprises one survey in the EU (2), together with models from The Netherlands (3) and the UK (4, 5) that predict the NCCC required to manage the workload in those countries.

The Working Group commenced its study in 2001 and at that time membership of the EU extended to the 15 established nations – Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, The Netherlands, Portugal, Spain, Sweden, and the UK.

The Working Group adopted the term 'consultant' to describe those senior laboratory medicine

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Table 1 Demographics of European Union countries in 2000.

Country	Population, × 10 ⁶	Area, km ²	Population density, n/km ²	Age distribution			Life expectancy, years		Fertility/ woman
				< 14 years	15–64 years	> 65 years	Male	Female	
Austria	8.1	83858	96.9	17	68	15	74.5	81.0	1.39
Belgium	10.2	30510	334.3	18	66	16	77.8	81.3	1.61
Denmark	5.3	43094	123.7	18	67	15	73.9	79.3	1.73
Finland	5.2	337030	15.3	18	67	15	73.7	81.2	1.70
France	59.3	547030	108.5	19	65	16	74.8	82.9	1.75
Germany	82.8	357021	231.9	16	68	16	74.3	80.7	1.38
Greece	10.6	131940	80.3	15	67	18	75.9	81.2	1.33
Ireland	3.8	70280	54.1	22	67	11	74.1	79.7	1.91
Italy	57.6	301230	191.3	14	68	18	75.8	82.4	1.18
Luxembourg	0.4	2586	170.1	19	67	14	73.8	80.6	1.70
Netherlands	15.9	41532	382.6	18	68	14	75.4	81.3	1.64
Portugal	10.0	92391	108.8	17	68	15	72.2	79.5	1.47
Spain	40.0	504750	79.2	15	68	17	75.3	82.5	1.15
Sweden	8.9	449964	19.7	19	65	16	75.0	80.5	1.74
UK	59.5	244820	243.0	19	65	16	75.0	80.5	1.74
Average				17.5	66.9	15.6	74.9	81.1	1.55
SD				2.0	1.3	1.8	1.4	1.1	0.22

specialists who have achieved the highest professional qualifications in each country and who have the competence and experience to be in clinical and scientific charge of a laboratory service. For the purposes of the study these individuals were referred to as consultant clinical chemists (CCC) and they were defined in terms of eligibility to join the European Register for Specialists in Clinical Chemistry and Laboratory Medicine (6). Eligibility applies to professionals having a primary university degree in medicine, biochemistry, chemistry, pharmacy or biological sciences, together with additional postdoctoral training in clinical laboratory sciences of at least 4 years (6).

The Working Group anticipated that it would see large differences in the NCCC across the 15 EU countries and so it undertook to relate these to a number of readily available national parameters. These parameters included: population demographics; gross domestic product (GDP); costs of healthcare; costs of in vitro diagnostic (IVD) testing; and the number of physicians and pharmacists.

The Working Group was aware that the scope of practice of clinical chemistry varies considerably across the EU (2) and so it undertook to derive a simple model that could take account of this variation and result in a more meaningful comparison of data across countries.

Methods

Data on the NCCC were obtained from the publication of Sanders et al. (2). The remaining information was collected via the Internet. Demographic data were obtained from The World Fact Book of the Central Intelligence Agency (CIA) (7). Data on healthcare professionals and healthcare expenditure were obtained from the World Health Organization (WHO) (8). Data on expenditure on IVD tests were obtained from the European Diagnostic Manufacturers Association (EDMA) (9).

Results

Table 1 records selected demographic data for the EC4 countries for the year 2000 (7). As expected, the size of the countries and the number of inhabitants differed considerably. The healthcare systems, and accordingly the systems used for laboratory medicine, coped with population densities ranging from 15.3 (Finland) to 382.6 inhabitants/km² (The Netherlands). In contrast, age distribution and life expectancy were remarkably similar across the 15 countries, reflecting a broadly similar standard of living and comparable demands on healthcare services. The total fertility rate per woman ranged from 1.15 (Spain) to 1.91 (Ireland).

Table 2 records the year 2000 costs of healthcare across the EU, expressed in terms of population and percentage GDP, together with the costs of IVD testing (9), which have been expressed in a similar way. There was a three-fold variation in the cost of healthcare per head of population from Portugal (€802) to Denmark (€2527). When expressed as a percentage of GDP, the cost of healthcare across the EC4 countries was less variable, ranging from 5.7% (Luxembourg, which has the highest GDP) to 10.5% (Germany). The cost of IVD testing did not follow the same pattern as the cost of healthcare. On a per capita basis, the cost of IVD testing increased from Greece (€8.1) to Austria (€19.4). The percentage of healthcare that was spent on IVD testing showed a three-fold variation from Denmark and The Netherlands (0.54%) to Portugal (1.71%).

In Table 3 the year 2000 costs of IVD testing from Table 2 are broken down by both instrumentation and reagents, and also across the major disciplines of laboratory medicine (9).

No major differences were evident in the results of this analysis. The instrument costs averaged 13.5% of total IVD test costs and ranged from 7% (Portugal) to 19% (Denmark). However, it is probable that the mar-

Table 2 Costs of healthcare and in vitro diagnostic testing in European Union countries in 2000.

Country	Population, × 10 ⁶	GDP pc, €	Health pc, €	Health, % GDP	IVD testing		
					Total, M€	Total pc, €	% Health
Austria	8.1	24,150	2008	8.3	157	19.4	0.96
Belgium	10.2	22,593	1998	8.8	190	18.6	0.93
Denmark	5.3	30,427	2527	8.3	72	13.5	0.54
Finland	5.2	23,581	1604	6.8	63	12.2	0.76
France	59.3	22,601	2159	9.6	999	16.9	0.78
Germany	82.8	24,098	2526	10.5	1467	17.9	0.71
Greece	10.6	11,673	938	8.0	85	8.1	0.86
Ireland	3.8	23,448	1426	6.1	33	8.8	0.62
Italy	57.6	18,987	1599	8.4	1076	18.9	1.18
Luxembourg	0.4	40,585	2316	5.7			
Netherlands	15.9	23,454	1971	8.4	167	10.6	0.54
Portugal	10.0	10,509	802	7.6	137	13.7	1.71
Spain	40.0	14,233	967	6.8	624	15.8	1.64
Sweden	8.9	24,592	2027	8.2	139	15.7	0.77
UK	59.5	21,482	1514	7.1	497	8.4	0.55
Average				7.9		14.2	0.90
SD				1.3		4.0	0.40

pc, per capita.

keting policies of the diagnostic companies vary between countries and that this affected the instrumentation/reagent breakdown observed. The distribution of expenditure by discipline was very similar across EC4 countries, with average figures that include clinical chemistry (30%), immunochemistry (25%), haematology (11%), infectious diseases (15%) and microbiology (6%).

Table 4 records the data available on the number of healthcare professionals employed in EC4 countries in the year 2000. These data were obtained from the survey of Sanders et al. (2) and from WHO (8). Large differences were evident in the NCCC, even when the data were expressed relative to 100,000 inhabitants, with a range from 0.6 (Germany) to 16.9 (France). Differences were also observed in the number of physicians per 100,000 population, but the rel-

ative differences were smaller, with a range from 164 (UK) to 554 (Italy). Expressing the NCCC as a function of 1000 physicians did nothing to narrow the variability of NCCC between countries, with a range from 1.7 (Germany) to 55.8 (France). A wide variation in the population-based number of pharmacists was also observed, with a range from 17.4 (Netherlands) to 145 (Finland). Reasons for these wide variations are suggested in the Discussion section of this paper.

From the data in Tables 1–4 we looked for correlations between the NCCC and a range of parameters, including population density, the costs of laboratory testing and the total costs of healthcare per capita. No meaningful correlations were observed.

A limited survey of the costs of IVD test kits in the EC4 countries was undertaken for one manufacturer (data not shown). This survey revealed that the prices

Table 3 Breakdown of in vitro diagnostic test costs in European Union countries in 2000.

Country	Population, × 10 ⁶	Cost of IVD testing			Cost of IVD testing, %				
		Total, M€	Inst, %	Reagent, %	Chem	Imc	Haem	Ser	Micro
Austria	8.1	157	13	87	29	29	13	12	4
Belgium	10.2	190	13	87	27	30	10	13	6
Denmark	5.3	72	19	81	21	25	9	21	5
Finland	5.2	63	13	87	37	23	10	11	6
France	59.3	999	15	85	23	25	12	17	8
Germany	82.8	1467	14	86	32	26	12	11	5
Greece	10.6	85	17	83	33	22	7	14	7
Ireland	3.8	33							
Italy	57.6	1076	11	89	24	27	15	18	6
Luxembourg	0.4								
Netherlands	15.9	167	16	84	31	24	10	12	8
Portugal	10.0	137	7	93	24	25	11	29	5
Spain	40.0	624	9	91	34	23	14	14	5
Sweden	8.9	139	11	89	42	21	11	13	3
UK	59.5	497	18	82	33	25	9	10	5
Average			13.5	86.5	30	25	11	15	6
SD			3.5	3.5	6.1	2.6	2.2	5.2	1.4

Inst, instrumentation; Chem, clinical chemistry; Imc, immunochemistry; haem, haematology; Ser, serology; Micro, microbiology.

Table 4 The number of healthcare professionals in European Union countries in 2000.

Country	Population, ×10 ⁶	NCCC		Physicians /10 ⁵	Pharmacists /10 ⁵	NCCC/1000 Physicians
		Total	/10 ⁵			
Austria	8.1	450	5.5	302	53	18.4
Belgium	10.2	910	8.9	395	145	22.6
Denmark	5.3	120	2.3	290	18	7.8
Finland	5.2	225	4.4	299	145	14.6
France	59.3	10,000	16.9	303	100	55.8
Germany	82.8	500	0.6	350	58	1.7
Greece	10.6	340	3.2	392	69	8.2
Ireland	3.8	90	2.4	219	78	11.0
Italy	57.6	8000	14.0	554	102	25.4
Luxembourg	0.4	56	13.0	272	69	47.9
Netherlands	15.9	315	2.0	251	17	8.0
Portugal	10.0	1000	10.0	312	75	32.1
Spain	40.0	450	1.1	424	113	2.7
Sweden	8.9	120	1.4	311	67	4.4
UK	59.5	1000	1.7	164	58	10.3
Total	375.0	23,576				
Average			5.8	322	78	18
SD			5.4	92	38	58

did differ between countries, but the range of difference was ~20%, too narrow a range to explain the wide range observed in IVD test costs per capita (Table 2).

The scope of work undertaken by clinical chemistry laboratories varies considerably across the EC4 countries (2). For example, in Ireland, Spain and the UK, clinical chemistry is a mono-speciality; clinical chemists do not undertake much haematology, immunology or microbiology. In contrast, all of these disciplines are overseen by clinical chemists in Austria, Belgium, France, Greece, Italy and Portugal (2). In order to reflect this different scope of practice, it was necessary to construct a simple staffing model that would amend the recorded NCCC to take account of the nature of the work undertaken by laboratory specialists in each country. Three countries in the EU (France, Italy and Luxembourg) have a laboratory medicine service that includes a large percentage of small private laboratories serving the primary care sector, and this differing service provision will have profound effects on the NCCC, which should also be reflected in the model.

The staffing model was derived pragmatically on the basis of three separate factors. Firstly, a starting figure of 10 consultants per million inhabitants was selected for the mono-speciality of clinical chemistry. Based on an approximate equivalence of workload parameters, additional numbers of consultants per million inhabitants were included for each speciality as follows: haematology, 10; serology, 7.5; microbiology, 12.5; and blood banking, 2. Secondly, it was recognised that every laboratory, no matter how small, will require a consultant, and so one additional consultant was added per private laboratory. Thirdly, an additional two consultants per million inhabitants was added in countries that do not have large numbers of private laboratories, in recognition of the growing laboratory consultant support required for the primary care sector.

Table 5 records the results of applying the staffing model to the survey data of Sanders et al. (2). A comparison of the actual NCCC with the number of consultants predicted by the model showed reasonable approximation in most countries. Overall, the model predicted 14% less consultants than the observed NCCC (20,166 vs. 23,576) and in all but five countries the number predicted was less than the number recorded. The model revealed France as the country with the greatest variation in actual numbers between predicted and recorded consultants, although in percentage terms Portugal showed the greatest model underprediction. In two countries (Germany and Sweden) the model predicted appreciably more consultants than observed.

Discussion

Any study of this nature is only as good as the quality of the data that are included. From the outset the Working Group recognised that none of the data it was going to use could be considered as 'hard' in the traditional sense of data derived by experimentation. Therefore, it sought to identify data that were objective and the most reliable that could be quoted from the literature. The year 2000 was selected as the year for data collection because this was the year in which the survey of Sanders et al. (2) was conducted. Data on demographics were obtained from the CIA and data on the number of healthcare professionals were obtained from WHO (8). The data on expenditure on IVD testing were obtained from EDMA (9). Nonetheless, the authors recognise limitations in the quality of the data and this is addressed later.

The demographic data in Table 1 were relatively non-controversial. The population data have been used in other tables to calculate different parameters against a population base. The data on age profile and life expectancy showed remarkable agreement

Table 5 Comparison of NCCC observed and numbers of consultants in laboratory medicine predicted from the staffing model.

Country	Population, × 10 ⁶	NCCC		Private laboratories	Speciality scope	Model prediction	
		Total	/10 ⁵			Consultants	Deviation
Austria	8.1	450	5.5		CHSMB	357	-21
Belgium	10.2	910	8.9		CHSMB	449	-51
Denmark	5.3	120	2.3		CH	117	-2
Finland	5.2	225	4.4		CHSB	163	-28
France	59.3	10,000	16.9	4000	CHSMB	6482	-35
Germany	82.8	500	0.6		CHS	2422	384
Greece	10.6	340	3.2		CHSMB	464	37
Ireland	3.8	90	2.4		C	45	-50
Italy	57.6	8000	14.0	5000	CHSM	7278	-9
Luxembourg	0.4	56	13.0	30	CHSMB	48	-14
Netherlands	15.9	315	2.0		CHSB	437	39
Portugal	10.0	1000	10.0		CHSMB	439	-56
Spain	40.0	450	1.1		C	473	5
Sweden	8.9	120	1.4		CHSB	279	133
UK	59.5	1000	1.7		C	712	-29
Total	375.0	23,576				20,166	-14
Average			5.8				
SD			5.4				

C, clinical chemistry; H, haematology; S, serology; M, microbiology; B, blood banking. Deviation: $100\% \times (\text{predicted} - \text{observed}) / \text{observed}$.

across the 15 countries. This was important for the remainder of the study, because it suggested that the demands on the national healthcare systems should be broadly similar. Differences in healthcare practice would reflect different workloads and expenditure, including in the area of laboratory medicine.

Evidence of different per capita expenditure on healthcare emerged from Table 2, with a three-fold range across the 15 countries. As may be anticipated, this difference is due in part to differences in per capita GDP. However, after correcting for GDP there is still a 1.8-fold range and this is only reduced to a 1.7-fold range by excluding Luxembourg, which has a tiny population and the highest per capita GDP. This difference in the percentage of GDP that is spent on healthcare is of great significance to governments and to the population of each country.

Against the background of differing GDP-corrected healthcare, it is interesting to note that there was a 3.1-fold difference in the percentage of the healthcare budget that was spent on IVD instruments and reagents. There was no correlation between the percentage of the healthcare budget that was spent on IVD testing and the overall GDP-corrected expenditure on healthcare (Table 2). Small differences in the costs of these products across the EU could not explain this major difference, nor could differences in the allocation of expenditure between instrumentation and reagents or between laboratory medicine disciplines (Table 3). It must be concluded that EU countries use their laboratory medicine services in different ways. Providing reasons for this observed difference is beyond the scope of this study.

The main focus of this study was to provide preliminary data on the number of consultants and senior laboratory professionals in each of the EU countries and to analyse this against published parameters. The only published source of this data is the NCCC (2). The initial analysis of the NCCC in Table 4 showed that

after correction for population differences there was still a 28-fold range in the NCCC across the countries studied. This variation was far greater than the 3.4-fold variation observed for the population-related number of consultant physicians. Expressing the NCCC as a function of the number of consultant physicians actually increased the range across countries from 28- to 33-fold and there was no simple relationship between NCCC and physicians.

The Working Group identified several factors that could contribute to the differences in the population-related NCCC. One of the major factors was the known difference across the EU in the scope of laboratory medicine that was recorded as clinical chemistry (2). In some countries clinical chemistry is a mono-speciality, whereas in other countries it includes some or all of haematology, serology and microbiology. In the former countries the recorded NCCC related only to consultants in the mono-speciality of clinical chemistry, while in the latter countries the NCCC included consultants in the other specialities. The description of the specialities used to describe the NCCC is included as part of Table 5 and, while this categorisation is approximate, it can serve to inform a simple staffing model.

There is no scientific validation of the staffing model derived. The derivation was pragmatic, based on experience of laboratory medicine, both in general and across the countries of the EU. Therefore, the data obtained from use of the model can at best be described as illustrative. The model took account of not only the specialities included in the NCCC, but also made allowance for the population served and support for primary care, either through predominantly central laboratories or through small private laboratories. Application of the staffing model resulted in the data recorded in Table 5 and it was apparent that there was a reasonable approximation between the observed total NCCC and the total number of con-

sultants predicted from the model. Furthermore, the previous ~30-fold range across the population-based NCCC was reduced to an approximate nine-fold range by application of the model.

Other factors could contribute to the approximate nine-fold range of variation in the number of consultants in laboratory medicine predicted by the staffing model. These factors include:

1. Errors in the data collected in the survey of Sanders et al. (2) due to misunderstanding or to distribution of the workforce across more than one professional society that submitted data;
2. Professionals included in the observed NCCC who work on a part-time rather than a full-time basis;
3. Inclusion in the NCCC of professionals, including technologists, who may not be consultants as defined in this study; and
4. True differences in the number of consultants in laboratory medicine reflecting differing practice.

Factors 1–3 would need to be eliminated before any meaningful conclusion could be reached on factor 4. There are no objective data published on factors 1–3, but there is subjective information from several national societies to indicate that factors 1–3 are real. These are addressed in alphabetical order:

- In France the clinical chemists cover all four disciplines of laboratory medicine. There are a substantial number of private laboratories and by law these are required to employ one laboratory specialist for every two technicians. As a result, large numbers of the consultants in the private laboratories do not hold full-time positions. Therefore, the 36% discrepancy between the observed NCCC and the number of consultants predicted by the model is almost certainly overstated.
- In Germany the NCCC observed was almost certainly too low. Until recently, medical and non-medical specialists in German laboratory medicine belonged to different professional societies and the data collected in the survey of Sanders et al. (2) only included data from one society. Inclusion of a corrected NCCC would help to reduce the outlier status of the population-based NCCC in Germany and the large difference between the NCCC observed and the number of consultants predicted from the model.
- In Ireland the recorded NCCC is higher than it should have been because of the inclusion of some senior technicians and sub-consultant-grade scientists.
- In Italy the clinical chemists cover all four disciplines of laboratory medicine and there are a large number of private laboratories. The number of consultants predicted by the model agrees well with the NCCC observed.
- In the Netherlands there are a small number of large laboratories containing laboratory specialists that oversee the disciplines of clinical chemistry, haematology and approximately half of the immunology testing. The small difference between the NCCC observed and the model-predicted consult-

ants is probably explained in part by economies of scale in which the ratio of consultants to technicians is relatively low.

- In Portugal the observed NCCC included an unknown number of clinical analysts (technicians), a fact that inflated the true NCCC and contributed to the underestimate by the staffing model.
- The NCCC for Spain refers only to monovalent clinical chemists and does not include any of the clinical analysts.
- In Sweden the NCCC observed was derived from one national society of medical consultants. Inclusion of data on laboratory specialists from other professional bodies would reduce the discrepancy between the NCCC observed and the number of consultants predicted by the model.
- Finally, in the UK there are ~250 medical consultants, ~250 consultant scientists and ~500 highly trained scientists who operate at sub-consultant level. Laboratory medicine is provided from relatively few large laboratories that employ large numbers of analysts (technicians) trained to degree level. Furthermore, variable but significant amounts of immunology and haematologic testing are carried out in UK clinical chemistry laboratories and this has not been allowed for in the model. This combination of factors can explain the discrepancy between the NCCC observed and the number of consultant predicted by the model.

It is clear from the preceding paragraphs that the quality of the data, particularly the NCCC, is far from perfect. Therefore, it is not possible to draw any meaningful conclusions from this study about the relative staffing, efficiency and differences in laboratory medicine practice across the countries of the EU. Despite these obvious shortcomings, the Working Group has prepared this document as a baseline study. The Working Group recommends that each of the countries in the EU seeks to obtain better quality data, particularly on the NCCC, and that each national society examines and comments on the validity of the suggested model to laboratory medicine practice in its country. The Working Group also believes that the data in this study will be of interest to the relevant national societies in the 10 countries that joined the EU during 2004.

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