

Perceptions of point-of-care infectious disease testing among European medical personnel, point-of-care test kit manufacturers, and the general public

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Background: The proper development and implementation of point-of-care (POC) diagnostics requires knowledge of the perceived requirements and barriers to their implementation. To determine the current requirements and perceived barriers to the introduction of POC diagnostics in the field of medical microbiology (MM)-POC a prospective online survey (TEMPOtest-QC) was established.

Methods and results: The TEMPOtest-QC survey was online between February 2011 and July 2012 and targeted the medical community, POC test diagnostic manufacturers, general practitioners, and the general public. In total, 293 individuals responded to the survey, including 91 (31%) medical microbiologists, 39 (13%) nonmedical microbiologists, 25 (9%) employees of POC test manufacturers, and 138 (47%) members of the general public. Responses were received from 18 different European countries, with the largest percentage of these living in The Netherlands (52%). The majority (>50%) of medical specialists regarded the development of MM-POC for blood culture and hospital acquired infections as “absolutely necessary”, but were much less favorable towards their use in the home environment. Significant differences in perceptions between medical specialists and the general public included the: (1) Effect on quality of patient care; (2) Ability to better monitor patients; (3) Home testing and the doctor-patient relationship; and (4) MM-POC interpretation. Only 34.7% of the general public is willing to pay more than €10 (\$13) for a single MM-POC test, with 85.5% preferring to purchase their MM-POC test from a pharmacy.

Conclusion: The requirements for the proper implementation of MM-POC were found to be generally similar between medical specialists and POC test kit manufacturers. The general public was much more favorable with respect to a perceived improvement in the quality of healthcare that these tests would bring to the hospital and home environment.

Keywords: Survey, questionnaire, point-of-care, microbial diagnosis

Introduction

Progress in the field of rapid and point-of-care (POC) diagnostics has been relatively slow, especially with respect to medical microbiology (MM) and the diagnosis of infectious diseases.¹ In particular, the culture of microorganisms such as bacteria and fungi on solid or liquid growth medium still remains the “gold standard” by which POC diagnostic tests in MM (MM-POC) are compared.² However, the identification of pathogens by culture, as well as the confirmation of their antimicrobial sensitivity profiles, are time consuming and require the skills of dedicated and trained medical

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laboratory personnel. Surrogate markers of infection are becoming available as rapid diagnostics for the determination of the presence or absence of an infection, including the measurement of C reactive protein and procalcitonin. Moreover, there is evidence to suggest that these surrogate markers may be useful in the detection of an infection in seriously ill patients in the nosocomial environment.³⁻⁶ Additionally, specific molecular and antibody based diagnostic methods are becoming more readily available in many medical disciplines, including virology, emergency medicine, etc.^{7,8} However, POC test (POCT) manufacturers have generally been slow in developing POC devices for the detection of infectious diseases, particularly for infections caused by bacterial and fungal pathogens, even though the development of such diagnostic devices would facilitate the rapid identification of these infectious agents (if present) and allow better targeted prescribing of suitable antimicrobial therapy.⁸ Further, the largest trend in the field of rapid microbiological diagnostics currently involves the evaluation and validation of new technologies within the medical microbiology laboratory per se, particularly the evaluation and validation of nucleic acid amplification technologies and mass spectrophotometric methods. This means that there still remains a large untapped market for the introduction of POC microbiological diagnostics for such target audiences as professional nonmicrobiologist medical professionals, general practitioners and even patients (within their own homes). The use of POC devices by the above mentioned target groups would provide tangible benefits for all concerned, including more accurate, rapid, and cheaper diagnosis of microbiological infections, whilst providing accompanying advantages with respect to national healthcare budgets; eg, by facilitating earlier discharge from hospital and helping reduce the use of staff and equipment,⁹⁻¹¹ and for example by shifting the burden of healthcare from healthcare providers to the actual patients themselves. Further, such market developments could provide significant advances with respect to limiting the ever growing threat of antimicrobial resistance and its impact on patient morbidity and mortality.^{12,13} In fact, the administration of suitable antibiotic therapy in the early onset of an infectious disease has been shown to improve the outcome of critically ill patients, with guidelines being available for the prescription of empirical antimicrobial therapy; ie, the prescribing of antimicrobial therapy before culture results become available.¹⁴ Moreover, the inappropriate use of antibiotics is closely linked to the development of antibiotic resistant microorganisms,¹⁵ and importantly, antibiotics are ineffective when used to treat viral infections. Further, the global increasing prevalence of

antimicrobial resistance has not gone unnoticed by regulatory bodies such as the National Institute of Health and the World Health Organization.

The European Union is also facing up to its responsibilities with respect to infectious disease diagnosis and the provision of improved healthcare to European citizens, having funded several projects that have investigated the development and potential of rapid and POC infectious disease diagnostics. In particular, the “TEMPOtest-QC” project (www.TEMPOtest-QC.eu) was designed to help “fill the current gap between microbiological POC testing technologies and actual clinical need”, and provide a “toolkit” (biobank of specimens, bacterial isolates, facilities and expertise, etc)¹⁶ to help small and medium-sized enterprises (SME) evaluate and validate new technologies during the development of MM-POC diagnostics. In this respect, one of the main tasks of the project was to help stakeholders (medical professionals, general practitioners, developers and manufacturers, and the general public) understand the perceptions and requirements for MM-POC diagnostics within hospital, general surgery, and home environments. In turn, the knowledge from this study will help the stakeholders to better understand the requirements and potential hurdles to the introduction of MM-POC devices into healthcare environments,^{17,18} be it the hospital laboratory, by the bedside, at the general practitioner’s surgery, or even within the patient’s own home.

Methods

Survey

As part of the TEMPOtest-QC project goals, an online survey was established in order to determine the views and perceived requirements of European citizens to infectious disease (bacterial/fungal) MM-POC testing (Supplemental Data Appendix S1). For some questions multiple answers were allowed, which means that for some questions the number of responses may be greater than the number of respondents. Target groups for the survey were: (1) hospital medical microbiologists, including medical microbiology laboratory technicians; (2) nonmedical microbiology specialists (hospital doctors and nurses); (3) POC test manufacturers (employees of POC test manufacturers); (4) the general public; and (5) general practitioners. The questionnaire remained open for online respondents from 08/16/2011 to 06/22/2012; a total of 10 months. These target groups were approached using: (1) an online website (www.tempotest-qc.eu); (2) a press release (“Join the fight against resistant bacteria!” by AlphaGalileo Foundation); (3) online social media, including YouTube (<http://www.youtube.com/watch?v=t1Ni8VtnFuI>), and relevant discussion groups

on Linked-In (www.linkedin.com); (4) an advertisement in a national Dutch free newspaper (Metro); (5) an advertisement in a local internal hospital newspaper (Ziekenhuiskrant); as well as (6) flyers and poster presentations at multiple European scientific conferences (Figure 1). The online and voluntary nature of the survey meant that we were unable to record the number of nonresponders. Moreover, the survey was designed so that all questions in the questionnaire had to be completed before the opinions of respondents could be successfully submitted.

Statistical analysis

The association between the categorical variables (answer and group) was assessed using the Chi-square test or Fisher's exact test when appropriate. Univariate logistic regression and odds ratio (OR) with 95% confidence intervals were calculated and used to compare the opinions of medical specialists and POCT manufacturers and the general public. Two sided *P*-values of <0.05 were considered significant. All analyses were performed using the statistical software package R (free download from <http://www.R-project.org/>) version 2.15.1 (The R Foundation for Statistical Computing, Vienna, Austria).¹⁹ In order to increase the sample size for

statistical analysis, the survey results of the hospital medical microbiologists target group ($n = 91$) were merged with the answers of the nonmicrobiology specialists ($n = 39$) and the combined group ($n = 130$) was referred to as "medical specialists".

Ethical statement

This study did not involve categorizing humans by race/ethnicity, age, disease/disabilities, religion, sex/gender, sexual orientation, or other socially constructed groupings. All results were collected anonymously using an online questionnaire which was available at www.TEMPOtest-QC.eu. The questionnaire asked volunteer respondents to provide their opinions on the development and potential hurdles to MM-POC testing. Although data was collected on country of employment, country of birth, and occupation, country of employment data was utilized to provide an indication of how successful the questionnaire "promotional campaign" was, and country of birth data was used to provide an indication of the geographical diversity of the respondent's opinions. Both country of birth and country of employ-

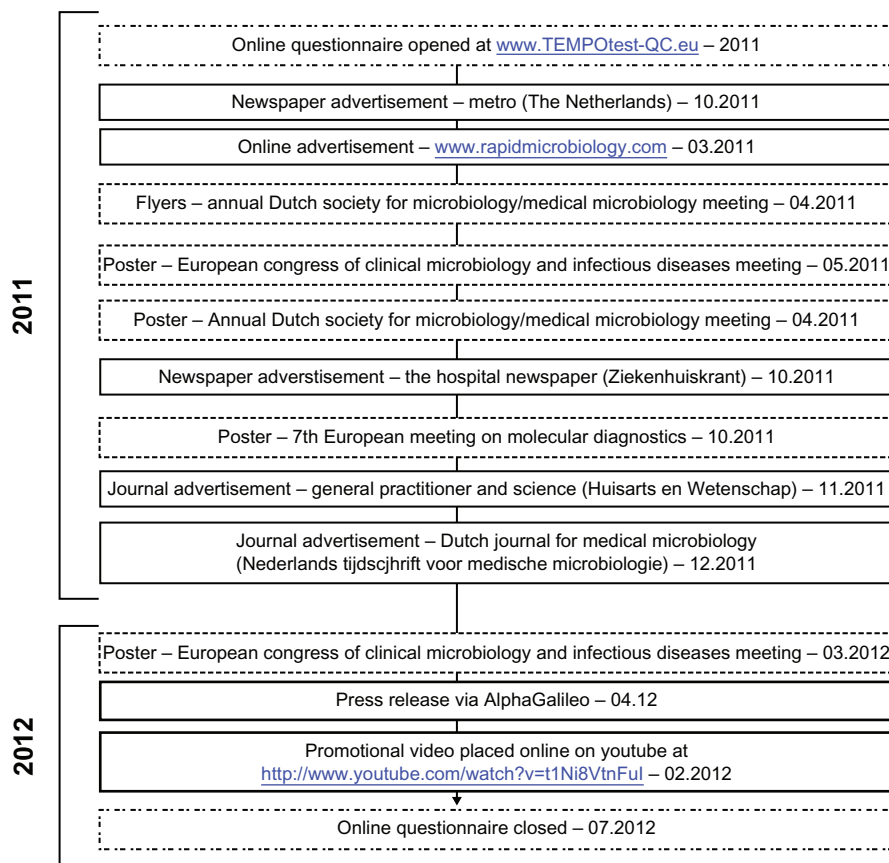


Figure 1 Table showing the timeline and activities associated with the dissemination of the TEMPOtest-QC questionnaire.

ment data were not used in subsequent statistical analyses of the results. Full details regarding the TEMPOtest-QC study protocol and objectives of the study were available online on the same webpage as the link to the questionnaire, and there was no compulsion for interested parties to participate in the questionnaire. For all of these reasons ethical approval for the study was not requested from the host institution (Erasmus Medical Center, Rotterdam, The Netherlands).

Results

Respondent characteristics

Overall, 293 individuals responded to the survey within the 10 months that the questionnaire was available online, with 91 (31%) participants responding as medical specialist (medical microbiologists), 39 (13%) as medical specialist (nonmedical microbiologists), 25 (9%) as employees of POC test manufacturers and 138 (47%) responding as members of the general public (Figure 2A). The largest percentage of these participants were born and living in The Netherlands, though responses were also received from respondents born or living in Poland, Italy, the United Kingdom, Belgium, and France among others (Figure 2B and C). In total, responses were received from respondents born and/or currently working in 18 different European countries. Responses were also received from eleven general practitioners practicing in The Netherlands. However, these results have been omitted due to the low numbers of respondents in this target group. Of the

medical microbiologist respondents, 24% reported to occasionally use a POC diagnostic device for the diagnosis of infectious diseases. The majority (68%) of medical microbiological point-of-care test (MM-POC) devices currently used were based on antibody related detection technologies.

POC infectious disease diagnostics and their specifications

As previously mentioned, the availability of POC diagnostics for (bacterial/fungal) infectious disease testing currently lags behind the availability of POC diagnostics in other fields of medicine, such as clinical chemistry and virology. Therefore, one of the first questions asked of the medical specialist (medical microbiologists and nonmicrobiologists) target groups was designed to obtain their opinions on how important an infectious disease (bacterial/fungal) POC diagnostic device would be in helping diagnose various infectious disease-related conditions. The majority of respondents considered MM-POC devices most useful in the diagnosis of blood culture infections, followed by hospital acquired infections and respiratory infections (Figure 3). There was less enthusiasm for the detection of oral and urinary tract infections. Interestingly, when asked for their opinions on the use of such MM-POC devices within various medical environments, there was a generally favorable response of medical specialists, POCT developers, and the general public for the use of MM-POC diagnostics in the hospital ward and general practitioners' surgeries. However, there appeared a sharp division in opinions on the use of MM-POC diagnostics at the patient's home (Figure 4), with

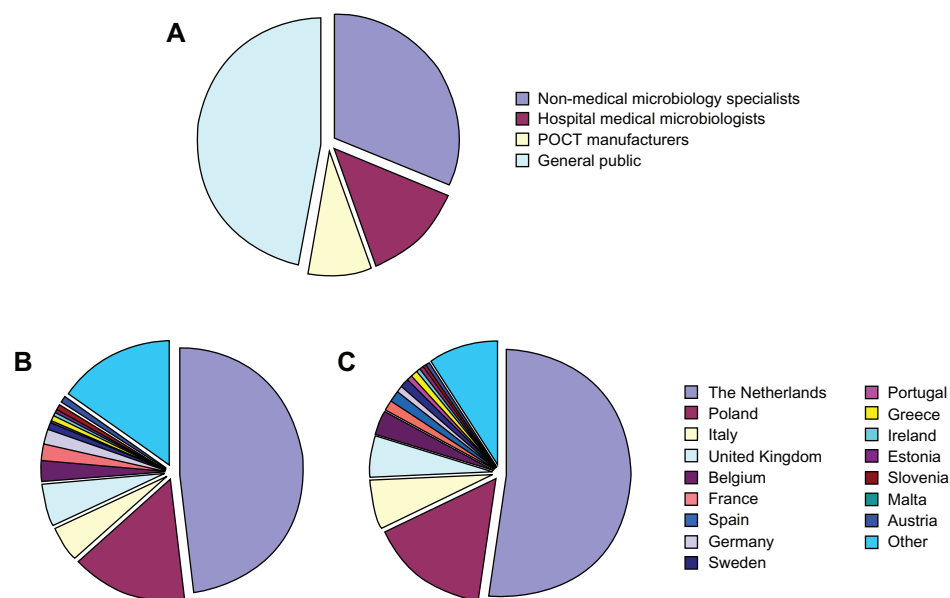


Figure 2 Profession (A), country born (B), and country of residence (C) of the 293 respondents who participated in the TEMPOtest-QC survey.
Abbreviation: POCT, point-of-care test.

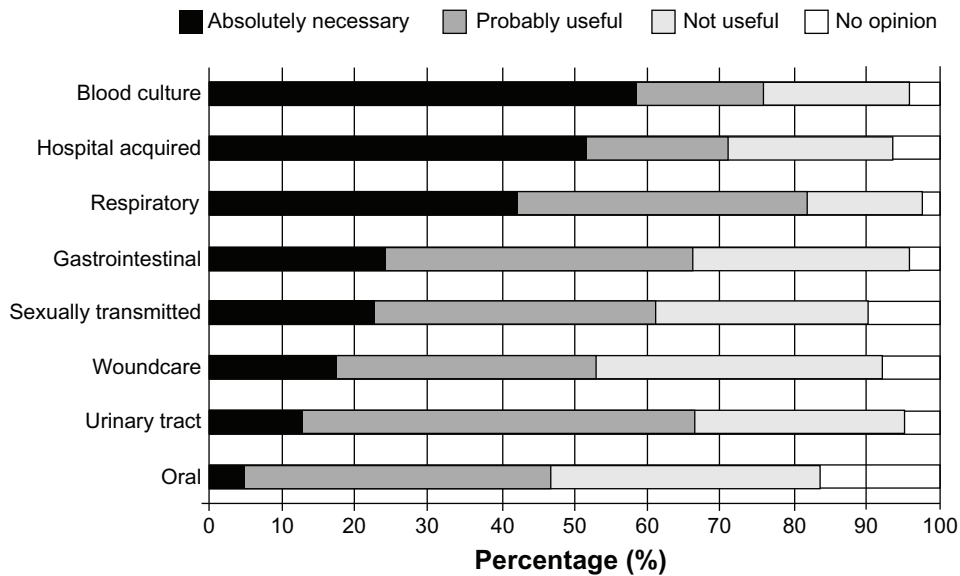


Figure 3 Mean responses of medical specialists regarding the current perceived necessity for MM-POC in relationship to type of disease. The majority regarded the development of MM-POC against both hospital acquired and blood culture infections as “Absolutely Necessary”.
Abbreviation: MM-POC, medical microbiological point-of-care tests.

greater than 60% of the general public having a favorable opinion, compared to less than 20% of medical specialists.

When asked about their opinions regarding the actual specifications of bacterial/fungal POC diagnostics, medical specialists and POC manufacturers provided the responses shown in Table 1. Opinions on the most important factors with respect to an MM-POC device indicated that no single particular factor was considered most important in any of the target groups, though “reliability” and “time to diagnosis”

tended to receive a large number of votes in both groups (both 60.8%). Interestingly, specificity scored high (60.0%) in the medical specialists group but was least favored by the POC manufacturer group (44.0%). Regarding the most important factors of an MM-POC device, no significant difference in the opinion of medical specialists and POCT manufacturers was observed ($P = 0.54$). Medical specialists opted for test specificity that could distinguish between bacteria, viruses, fungi and no infection (57.7%) and class of antibiotic resistance

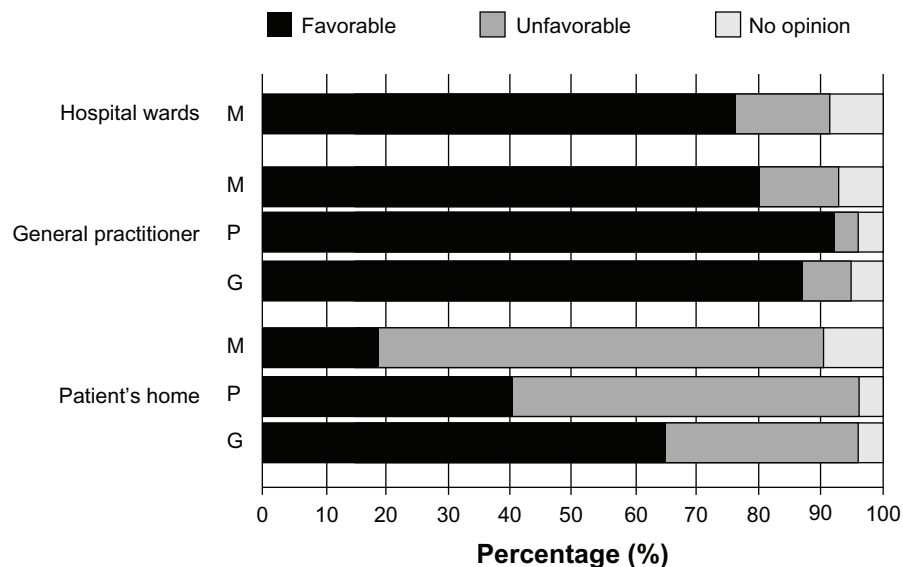


Figure 4 Opinions of target groups regarding the use of infectious disease (bacterial/fungal) POC devices in different environments. Medical specialists (hospital medical microbiologists and nonmedical microbiology specialists) (M), POCT manufacturers (P), and the general public (G) regarding the applicability of MM-POC in hospital wards, at the general practitioner or at the patient's home.
Abbreviations: G, general practitioners; M, medical specialists; P, POCT manufacturers; POCT, point-of-care test; MM-POC, medical microbiological point-of-care tests.

Table 1 Opinions of target groups regarding the most relevant specifications for bacterial or fungal point-of-care diagnostics

	Medical specialists No (%)	POCT manufacturers No (%)	OR (95% CI)	P-value
Respondents	130	25		
1. In your opinion, what are the most important factors with respect to infectious disease POCT? (multiple answers allowed).				
Costs	70 (53.8)	17 (68.0)	–	0.543
Sensitivity	78 (60.0)	14 (56.0)	–	–
Specificity	78 (60.0)	11 (44.0)	–	–
Simplicity	69 (53.1)	19 (76.0)	–	–
Reliability	79 (60.8)	19 (76.0)	–	–
Time to diagnosis	79 (60.8)	21 (84.0)	–	–
2. How specific should a bacterial or fungal POCT be? The test should be able to distinguish between: (multiple answers allowed).				
Bacteria/fungi/viruses/no infection	75 (57.7)	9 (36.0)	–	0.543
Bacterial or fungal species including genetic types/clones	56 (43.1)	16 (64.0)	–	–
Class of antibiotic resistance	94 (72.3)	12 (48.0)	–	–
No opinion	9 (6.9)	2 (8.0)	–	–
3. What would be your preferred maximum “time to diagnosis” for a bacterial or fungal POCT?				
0 minutes–5 minutes	10 (7.7)	4 (16.0)	0.40 (0.11–1.20)	0.121
5 minutes–15 minutes	36 (27.7)	7 (28.0)	0.44 (0.11–1.93)	0.251
15 minutes–1 hour	50 (38.5)	9 (36.0)	0.21 (0.04–1.12)	0.068
>1 hour	32 (24.6)	3 (12.0)	0.42 (0.11–1.77)	0.206
4. Complexity: In your opinion, what is the maximum number of processing steps that should be performed when using a bacterial or fungal POCT?				
1 step	22 (16.9)	7 (28.0)	0.32 (0.13–0.71)	0.008
2 steps	47 (36.2)	5 (20.0)	0.32 (0.09–1.11)	0.075
3 steps	42 (32.3)	10 (40.0)	0.68 (0.23–2.10)	0.494
>3 steps	16 (12.3)	3 (12.0)	0.45 (0.09–1.85)	0.289

Abbreviations: CI, confidence interval; No, number; OR, odds ratio; POCT, point-of-care test.

(72.3%). A similar result was obtained among the POCT manufacturers. Interestingly both target groups tended to agree that any such MM-POC test should possess a maximum “time-to-diagnosis” of 15 min–1 hour. In addition, according to the target groups, the maximum number of processing steps for an MM-POC device was considered as 2 to 3 processing steps, which on average, when combined with the maximum time-to-diagnosis results described above, would suggest that an MM-POC device should require an average processing time of approximately 15 minutes per step.

POC disease diagnosis at home and the quality of healthcare

Table 2 shows the opinions of hospital personnel and the general public to questions relating to POC infectious disease diagnosis at home and the perceptions of these target groups regarding the quality of POC healthcare. The large majority of both medical specialists and the general public thought that the introduction of bacterial or fungal POC diagnostic testing to the general practi-

tioner’s surgery, or within the patient’s own home, would affect the quality of patient care. However, the opinion on how patient care is affected significantly differed between the two target groups. The majority (72.5%) of the general public expects that the use of MM-POC will allow the doctor to better monitor their health compared to less than half (40.0%) of the medical specialists. The general public tended to be more positive regarding the effect of home POC testing on the doctor-patient relationship than the medical specialists. In fact, most medical specialists thought that bacterial or fungal home-testing POC technologies would indeed affect the doctor-patient relationship, with the majority of these (37/62) believing that any effect would result in a negative rather than a positive impact. Also the opinions on interpretation of the MM-POC test results differed between the two target groups. Whereas most (53.1%) of the medical specialists expect problems in the interpretation of POC test results, a significantly smaller percentage (37.0%) of the general public foresees problems.

Table 2 Opinions of target groups regarding the effect of point-of-care testing on the quality of health care

	Medical specialists No (%)	General public No (%)	OR (95% CI)	P-value
Respondents	130	138		
1. In your opinion, would the introduction of bacterial or fungal POC diagnostic testing to the general practitioner's surgery, or within the patient's own home, affect the quality of patient care?				
Yes	76 (58.5)	101 (73.2)	0.34 (0.15–0.71)	0.006
No	28 (21.5)	28 (20.3)	2.79 (1.14–7.27)	0.028
Don't know	24 (18.5)	9 (6.5)	3.47 (1.59–8.22)	0.003
2. Do you think that home-testing using bacterial or fungal POC testing technologies will allow you/the doctor to better monitor your patients/your health?				
Yes	52 (40.0)	100 (72.5)	1.75 (1.27–2.44)	<0.0001
No	48 (36.9)	25 (18.1)	0.28 (0.15–0.49)	<0.0001
Don't know	28 (21.5)	13 (10.0)	0.24 (0.11–0.48)	<0.0001
3. Do you think that home-testing using bacterial or fungal POC technologies will have an impact on the doctor-patient relationship?				
Yes (in a positive context)	25 (19.2)	48 (34.8)	1.66 (1.05–2.65)	0.032
Yes (in a negative context)	37 (28.5)	30 (23.1)	0.45 (0.23–0.87)	0.019
No	27 (20.8)	35 (25.4)	0.73 (0.37–1.43)	0.359
Don't know	39 (30.0)	25 (18.1)	0.37 (0.18–0.72)	0.004
4. Do you think that there will be significant problems in interpreting the results of bacterial or fungal POCT?				
Yes	69 (53.1)	51 (37.0)	0.68 (0.47–0.97)	0.033
No	33 (25.4)	47 (34.1)	1.87 (1.07–3.28)	0.028
Don't know	26 (20.0)	40 (29.0)	2.18 (1.20–4.02)	0.012

Abbreviations: CI, confidence interval; No, number; OR, odds ratio; POC, point-of-care; POCT, point-of-care test.

Infectious disease POC diagnostics and the general public

One of the questions in the survey was related to the effect of MM-POC on patient visits to the general practitioner. The majority of the general public respondents (46.4%) expect that the introduction of MM-POC tests will lead to a decrease in the number of visits they make to the general practitioner (Table 3). Additionally, if these MM-POC devices are to become available on the home testing market for the general public, information is required regarding the financial expectations of the general public towards the cost of such POC devices. The most favorable price for a single POC test currently lies between €5 to €10 (approximately \$7.5–\$12.5) per test (Table 3). Finally, 85.5% of the general public would be willing to purchase an MM-POC testing device at a pharmacy, rather than at a supermarket, at a drugstore, or over the internet (Table 3).

Discussion

The worldwide introduction and frequent use of infectious disease POC diagnostic devices (including bacterial/fungal testing), will help reduce the global infectious disease burden and help reduce the continuing development and spread of

antimicrobial resistances. The TEMPOtest-QC questionnaire revealed that the development of MM-POC devices for the diagnosis of blood borne, hospital acquired, and respiratory tract infections should have the highest priority for POCT manufacturers. Moreover we would recommend POCT manufacturers to target MM-POC devices which are able to distinguish between bacteria/fungi/viruses/ no infection, and/or class of antibiotic resistance, with a maximum “time-to-diagnosis” of 15–60 minutes, in which a maximum of 2–3 processing steps are involved. All factors regarding infectious disease POC listed in the survey were scored with an equal importance by both medical specialists and POCT manufacturers. Interestingly, the only exception was specificity; this factor scored highest in the medical specialists group but was least favored by the POCT manufacturer group. Perhaps this is a factor that needs to be re-considered by POCT developers and manufacturers?

Surprisingly, “costs” tended not to be a top priority for both groups, though this was possibly due to the fact that the medical specialists were considering the use of MM-POC devices within a medical environment (hospital or general practitioner's surgery), rather than considering MM-POC devices intended for use in the much less mature

Table 3 Perceived effect of the introduction of bacterial or fungal point-of-care testing technologies according to the general public

	General public No (%)
Respondents	138
1. Do you think that home-testing using bacterial or fungal POCT technologies will likely increase or decrease the number of visits you make to your general practitioner?	
Increase	16 (11.6)
Decrease	64 (46.4)
Have no effect	39 (28.3)
Don't know	19 (13.8)
2. If a home-testing kit for infectious diseases was available what is the maximum cost that you would be prepared to pay for a single test?	
€ 0,-	6 (4.3)
€ 1,- to € 5	30 (21.7)
€ 5,- to € 10	54 (39.1)
€ 10,- to € 25	38 (27.5)
€ 25,- to € 50	6 (4.3)
€ 50,- to € 100	3 (2.2)
>€ 100	1 (0.7)
3. Where would you prefer to purchase an infectious disease home-testing kit? (multiple choices allowed).	
Your local hospital	21 (15.2)
General practitioner	42 (30.4)
Pharmacy	118 (85.5)
Drugstore	48 (34.8)
Supermarket	16 (11.6)
Internet	19 (13.8)

Abbreviations: No, number; POCT, point-of-care test.

“home-testing” environment. Perhaps encouraging for POC manufacturers, the price that the general public is willing to pay is above the current price for a single POC test as declared by POCT manufacturers (data not shown). Though of course this price may have been calculated using discounts available from high-volume sales and high-throughput sampling, as opposed to the single-use testing that will be required for consumers within their own home. The purchase of an MM-POC device is by the majority of the general public favored at a pharmacy. This may be related to “trust issues”, the general public perceiving medical products sold at pharmacies as being perhaps more “trustworthy” and of higher quality, as well as possibly valuing the expert advice available at pharmaceutical stores.

As a note of concern for POC manufacturers, respondents in the medical specialist and general public target groups were significantly different with respect to their opinions on whether there would be significant problems in interpreting the results of MM-POC diagnostic tests. In contrast, however, a clear majority of medical specialists thought that there would be significant problems in interpretation, a point of

concern also raised in a previous study.²⁰ These results indicate that careful design, unambiguous result interpretation, and ready access to reliable and understandable diagnostic information is a prerequisite for building consumer confidence in the use of POC diagnostics.

The authors acknowledge there is a bias in the national reporting levels between the different European countries in this study. However, at the moment there is no evidence to suggest that the opinions of Dutch and Polish responders are different to those of other European citizens. The authors also acknowledge that the responses from POCT manufacturers may be biased towards the rapid introduction of MM-POC devices to the infectious diseases diagnostic market. In fact, the responses from POCT manufacturers were similar to the opinions of those of medical professionals, and it is the favorable opinion of the general public, which is currently the driving force behind the development and implementation of such MM-POC devices.

In conclusion, in this survey, no significant differences were observed between the opinions of medical specialists and POC manufacturers regarding the most relevant specifications for MM-POC devices. However, interesting differences were observed in the responses to the introduction of MM-POC devices and their effect on the quality of healthcare, with the general public tending to be more optimistic about the effect of MM-POC device implementation and subsequent improvement in the quality of healthcare compared to the medical specialists. All of the above mentioned issues need to be addressed, in order to successfully understand the current requirements and perceived hurdles to the implementation of MM-POC diagnostic devices into the medical, and possibly home environment.

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Disclosure

The authors report no conflicts of interest in this work.

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Supplemental data appendix S1

Nonmedical microbiology specialist (hospital doctors and nurses)

Q no	Labels	Question	Options
1.	a)	Do you use bacterial or fungal "point-of-care" test(s) for the diagnosis of infectious diseases at the moment?	Yes No
	b)	If yes, which type of bacterial or fungal "point-of-care" test(s) do you use? (multiple answers allowed).	Nucleic acid based Antibody based Protein based Metabolomic Don't know Other
	c)	If no, would you be willing to use an bacterial or fungal "point-of-care" test in your hospital ward in the future?	Yes No Perhaps Don't know
2.		In your opinion, what are the most important factors with respect to infectious disease "point-of-care" testing? (multiple answers allowed).	Costs Sensitivity Specificity Simplicity Reliability Time to diagnosis
3.		How specific should a bacterial or fungal "point-of-care" test be? The test should be able to distinguish between ...	Bacteria or fungi or viruses or no infection only Bacterial/fungal species Bacterial/fungal sub-species and major genetic types and clones Class of antibiotic resistance (eg, cephalosporin, aminoglycoside, fluoroquinolone, etc) Actual antibiotic resistance gene present No opinion
4.		Please rank the following infectious diseases where you think a bacterial or fungal "point-of-care" test(s) would be particularly useful at the present moment in time.	Respiratory/gastrointestinal/sexually transmitted diseases/urinary tract infections/woundcare/oral infections/hospital acquired infections/blood culture infections Absolutely necessary/probably useful/not useful/no opinion
5.		What would be your preferred maximum "time to diagnosis" for a bacterial or fungal "point-of-care" test?	0 minutes to 5 minutes 6 minutes to 15 minutes 16 minutes to 30 minutes 31 minutes to 60 minutes 1 to 2 hours 2 to 5 hours >5 hours
6.		Complexity: in your opinion, what is the maximum number of processing steps that should be performed when using a bacterial or fungal "point-of-care" test?	1 step 2 steps 3 steps 4 steps >4 steps
7.		What is your opinion on the introduction of bacterial or fungal "point-of-care" diagnostic testing within your own hospital wards?	Very favorable Favorable Unfavorable Very unfavorable No opinion
8.		What would be your opinion if bacterial or fungal "point-of-care" testing became available within the general practitioner's surgery?	Very favorable Favorable Unfavorable Very unfavorable No opinion

(Continued)

Nonmedical microbiology specialist (hospital doctors and nurses) (Continued)

Q no	Labels	Question	Options
9.		What would be your opinion if bacterial or fungal "point-of-care" testing became available within the patient's own home (with patients able to perform their own diagnostic testing)?	Very favorable Favorable Unfavorable Very unfavorable No opinion
10.	a)	In your opinion, would the introduction of bacterial or fungal "point-of-care" testing to hospital wards (to be performed by nonmedical microbiology specialist doctors and nurses), affect your professional status?	Definitely yes Yes No Definitely no Don't know
	b)	If yes, how do you think it would affect your professional status?	Very positively Positively Negatively Very negatively Don't know
11.		Do you think that home-testing using bacterial or fungal point-of-care testing technologies will:	
	a)	Allow you to better monitor your patients?	Yes No Don't know
	b)	Negatively affect your dealings with patients?	Yes No Don't know
	c)	Have impact on the doctor-patient relationship?	Yes (in a positive context) Yes (in a negative context) No Don't know
12.		Do you think that there will be significant problems in interpreting the results of bacterial or fungal "point-of-care" diagnostic tests?	Yes No Don't know
13.		In your opinion, would the introduction of bacterial or fungal "point-of-care" diagnostic testing to the general practitioner's surgery, or within the patient's own home, affect the quality of patient care?	Definitely yes Yes No Definitely no Don't know
14.		What is your opinion on the following statements:	
	a)	"Infectious disease home-testing kits are being developed that will allow people to test themselves at home without medical supervision for the presence of infectious diseases?"	Very favorable Favorable Unfavorable Very unfavorable No opinion
	b)	"Test-kits are being developed that will allow people to be tested at their own general practitioner's surgery for the presence of infectious diseases?"	Very favorable Favorable Unfavorable Very unfavorable No opinion
15.		Do you believe that the use of bacterial and fungal "point-of-care" test(s) will positively or negatively affect how patients view your profession?	Very positively Positively Negatively Very negatively Don't know No effect

Hospital medical microbiologists including medical microbiology laboratory technicians

Q no	Labels	Question	Options	Option labels
1.	a)	Do you use bacterial or fungal “point-of-care” test(s) for the diagnosis of infectious diseases at the moment?	Yes No	a b
	b)	If yes, which type of bacterial or fungal “point-of-care” test(s) do you use? (multiple answers allowed).	Not applicable Nucleic acid based Antibody-based Protein-based Metabolomic Don't know Other	a b c d e f
	c)	If no, would you be willing to use an bacterial or fungal “point-of-care” test in your hospital ward in the future?	Yes No Perhaps Don't know	a b c d
2.		In your opinion, what are the most important factors with respect to infectious disease “point-of-care” testing? (multiple answers allowed).	Costs Sensitivity Specificity Simplicity Reliability Time to diagnosis	a b c d e f
3.		How specific should a bacterial or fungal “point-of-care” test be? The test should be able to distinguish between ...	Bacteria or fungi or viruses or no infection only Bacterial/fungal species Bacterial/fungal sub-species and major genetic types and clones Class of antibiotic resistance (eg, cephalosporin, aminoglycoside, fluoroquinolone, etc) Actual antibiotic resistance gene present No opinion	a b c d e f
4.		Please rank the following infectious diseases where you think a bacterial or fungal “point-of-care” test(s) would be particularly useful at the present moment in time.	Respiratory/gastrointestinal/sexually transmitted diseases/urinary tract infections/woundcare/ oral infections/hospital acquired infections/blood culture infections Absolutely necessary/probably useful/not useful/ no opinion	
5.		What would be your preferred maximum “time to diagnosis” for a bacterial or fungal “point-of-care” test?	0 minutes to 5 minutes	a
			6 minutes to 15 minutes	b
			16 minutes to 30 minutes	c
			31 minutes to 60 minutes	d
			1 to 2 hours	e
			2 to 5 hours	f
6.		Complexity: in your opinion, what is the maximum number of processing steps that should be performed when using a bacterial or fungal “point-of-care” test?	>5 hours	g
			1 step	a
			2 steps	b
			3 steps	c
			4 steps	d
7.		What is your opinion on the introduction of bacterial or fungal “point-of-care” diagnostic testing within your own hospital wards?	>4 steps	e
			Very favorable	a
			Favorable	b
			Unfavorable	c
			Very unfavorable	d
8.		What is your opinion on the introduction of bacterial or fungal “point-of-care” diagnostic testing to the general practitioner’s surgery?	No opinion	e
			Very favorable	a
			Favorable	b
			Unfavorable	c
			Very unfavorable	d
		No opinion	e	

(Continued)

Hospital medical microbiologists including medical microbiology laboratory technicians (*Continued*)

Q no	Labels	Question	Options	Option labels
9.		What would be your opinion if bacterial or fungal "point-of-care" diagnostic testing became available within the patient's own home (with patients able to perform their own diagnostic testing)?	Very favorable Favorable Unfavorable Very unfavorable No opinion	a b c d e
10.	a)	In your opinion, would the introduction of bacterial or fungal "point-of-care" testing to hospital wards (to be performed by nonmedical microbiology specialist doctors and nurses), affect your professional status?	Definitely yes Yes No Definitely no Don't know	a b c d e
	b)	If yes, how do you think it would affect your professional status?	Very positively Positively Negatively Very negatively Don't know	a b c d e
11.		Do you think that home-testing using bacterial or fungal "point-of-care" testing technologies will:		
	a)	Allow you to better monitor your patients' health?	Yes No Don't know	a b c
	b)	Allow patients to better monitor their health?	Yes No Don't know	a b c
	c)	Increase or decrease the number of visits patients make to their general practitioner?	Greatly increase Increase Decrease Greatly decrease Have no effect Don't know	a b c d e f
	d)	Impact on the doctor-patient relationship?	Yes (in a positive context) Yes (in a negative context) No Don't know	a b c d
12.		Do you think that there will be significant problems in interpreting the results of bacterial or fungal "point-of-care" diagnostic tests?	Yes No Don't know	a b c
13.		In your opinion, would the introduction of bacterial or fungal "point-of-care" diagnostic testing to the general practitioner's surgery, or within the patient's own home, affect the quality of patient care?	Definitely yes Yes No Definitely no Don't know	a b c d e
14.		What is your opinion on the following statements:		
	a)	"Infectious disease home-testing kits are being developed that will allow people to test themselves at home without medical supervision for the presence of infectious diseases?"	Very favorable Favorable Unfavorable Very unfavorable No opinion	a b c d e
	b)	"Test-kits are being developed that will allow people to be tested at their own general practitioner's surgery for the presence of infectious diseases?"	Very favorable Favorable Unfavorable Very unfavorable No opinion	a b c d e
15.		Do you believe that the use of bacterial and fungal point-of-care test(s) will positively or negatively affect how patients view your profession?	Very positively Positively Negatively Very negatively Don't know No effect	a b c d e f

(Continued)

Hospital medical microbiologists including medical microbiology laboratory technicians (*Continued*)

Q no	Labels	Question	Options	Option labels
16.		In your opinion, would the introduction of bacterial or fungal “point-of-care” diagnostic testing to the general practitioner’s surgery, or within the patient’s own home, affect the jobs of currently employed medical microbiologists?	Definitely yes Yes No Definitely no Don’t know	a b c d e
17.		In your opinion, would there still be a role for qualified hospital medical microbiologists and trained medical microbiology diagnostic laboratory technicians if bacterial or fungal “point-of-care” diagnostic testing became widely available and used in hospital wards, in general practitioners surgeries, and at home by patients?	Definitely yes Yes No Definitely no Don’t know	a b c d e

Point-of-care test manufacturers

Q no	Labels	Question	Options	Option labels
1.		Which type of bacterial or fungal “point-of-care” test (including tests available to general practitioners, hospital laboratories, and in the home) do you currently have available on the market? (multiple answers allowed).	Nucleic acid based Antibody based Protein based Metabolomic Other No test currently available	a b c d e f
2.		In your opinion, what are the most important factors with respect to infectious disease “point-of-care” testing? (multiple answers allowed).	Costs Sensitivity Specificity Simplicity Reliability Time to diagnosis	a b c d e f
3.		How specific should a bacterial or fungal “point-of-care” test be? The test should be able to distinguish between ...	Bacteria or fungi or viruses or no infection only Bacterial/fungal species Bacterial/fungal sub-species and major genetic types and clones Class of antibiotic resistance (eg, cephalosporin, aminoglycoside, fluoroquinolone, etc) Actual antibiotic resistance gene present No opinion	a b c d e f
4.	a)	For which disease type(s) have you developed, or are you developing, a “point-of-care” test? (multiple answers allowed).	Respiratory Gastrointestinal Sexually transmitted diseases Urinary tract infections Woundcare Oral infections Hospital acquired infections Blood culture infections None Confidential	a b c d e f g h i j
	b)	Which infectious disease type is likely to be most profitable for manufacturers of infectious disease “point-of-care” tests? Please rank in order of importance.	Respiratory Gastrointestinal Sexually transmitted diseases	Absolutely necessary/probably useful/not useful/no opinion Absolutely necessary/probably useful/not useful/no opinion Absolutely necessary/probably useful/not useful/no opinion

(Continued)

Point-of-care test manufacturers (Continued)

Q no	Labels	Question	Options	Option labels
			Urinary tract infections	Absolutely necessary/probably useful/not useful/no opinion
			Woundcare	Absolutely necessary/probably useful/not useful/no opinion
			Oral infections	Absolutely necessary/probably useful/not useful/no opinion
			Hospital acquired infections	Absolutely necessary/probably useful/not useful/no opinion
			Blood culture infections	Absolutely necessary/probably useful/not useful/no opinion
5.		How long do you estimate the time to diagnosis for your bacterial or fungal "point-of-care" test to be?	0 minutes to 5 minutes	a
			6 minutes to 15 minutes	b
			16 minutes to 30 minutes	c
			31 minutes to 60 minutes	d
			1 to 2 hours	e
			2 to 5 hours	f
			>5 hours	g
			Not known	h
			Confidential	i
			Not applicable	j
6.		Complexity: in your opinion, what is the maximum number of processing steps that should be performed when using a bacterial or fungal "point-of-care" test?	1 step	a
			2 steps	b
			3 steps	c
			4 steps	d
			>4 steps	e
7.		How much does your "point-of-care" cost (per test) on the market (in euro)?	€ 0,- per test	a
			€ 1,- to € 5,- per test	b
			€ 6,- to € 10,- per test	c
			€ 11,- to € 25,- per test	d
			€ 26,- to € 50,- per test	e
			€ 51,- to € 100,- per test	f
			>€ 100,- per test	g
			Not known	h
			Confidential	i
			Not applicable	j
8.		In your opinion, would the introduction of bacterial or fungal "point-of-care" diagnostic testing to the general practitioner's surgery, or within the patient's own home, affect the quality of patient care?	Definitely yes	a
			Yes	b
			No	c
			Definitely no	d
			Don't know	e
9.		What is your opinion on the following statements:		
	a)	"Infectious disease home-testing kits are being developed that will allow people to test themselves at home without medical supervision for the presence of infectious diseases?"	Very favorable	a
			Favorable	b
			Unfavorable	c
			Very unfavorable	d
			No opinion	e
	b)	"Test-kits are being developed that will allow people to be tested at their own general practitioner's surgery for the presence of infectious diseases?"	Very favorable	a
			Favorable	b
			Unfavorable	c
			Very unfavorable	d
			No opinion	e
10.		Do you believe that the use of bacterial and fungal point-of-care test(s) will positively or negatively affect how patients view your profession?	Very positively	a
			Positively	b
			Negatively	c
			Very negatively	d
			Don't know	e
			No effect	f

(Continued)

Point-of-care test manufacturers (Continued)

Q no	Labels	Question	Options	Option labels
11.		Which type of bacterial or fungal “point-of-care” test (including tests available to general practitioners, hospital laboratories, and in the home) are you currently developing? (multiple answers allowed).	Nucleic acid based Antibody based Protein based Metabolomic Other No test currently available Confidential	a b c d e f g
12.		For which market have you, or are you, developing your bacterial or fungal “point-of-care” tests?	General practitioners Hospital laboratories Home use Confidential Not applicable	a b c d e
13.		Which factors would/do you take into consideration if/when developing new bacterial or fungal “point-of-care” tests? Please rank in importance.	Size of target audience Profit margin Prevalence of disease Costs of manufacture Ease of use for the end-user Costs of kit development Reputation of kit manufacturer	a b c d e f g
14.		Which factor(s) do you think are the most important in influencing hospitals and general practitioners to use bacterial or fungal “point-of-care” tests for a diagnostics laboratory? Please rank in importance.	Cost per test Simplicity of test methodology Speed of diagnosis Robustness and reliability of the test kit Ease of use for the end-user Reputation of the manufacturer Sensitivity Specificity	a b c d e f g h

General public

Q no	Labels	Question	Options	Option labels
1.		What is your opinion on the use of infectious disease home-testing-kits that would allow you to monitor your health at home?	Very favorable Favorable Unfavorable Very unfavorable No opinion	a b c d e
2.		If a home-testing kit for infectious diseases was available, what is the maximum time that you would be prepared to wait for a result?	0 minutes to 5 minutes 6 minutes to 15 minutes 16 minutes to 30 minutes 31 minutes to 60 minutes 1 to 2 hours 2 to 5 hours >5 hours	a b c d e f g
3.		If a home-testing kit for infectious diseases was available (and you had to purchase the kit yourself) what is the maximum cost that you would be prepared to pay for a single test (in euro)?	€ 0,- per test € 1,- to € 5,- per test € 6,- to € 10,- per test € 11,- to € 25,- per test € 26,- to € 50,- per test € 51,- to € 100,- per test >€ 100,- per test	a b c d e f g
4.	a)	Do you think that home-testing using bacterial or fungal “point-of-care” testing technologies will: Allow you to better monitor your health?	Yes No Don't know	a b c

(Continued)

General public (Continued)

Q no	Labels	Question	Options	Option labels
	b)	Allow a doctor to better monitor your health?	Yes No Don't know	a b c
	c)	Likely increase or decrease the number of visits you make to your general practitioner?	Greatly increase Increase Decrease Greatly decrease Have no effect Don't know	a b c d e f
	d)	Impact on the doctor-patient relationship?	Yes (in a positive context) Yes (in a negative context) No Don't know	a b c d
5.		Do you think that there will be significant problems in interpreting the results of bacterial or fungal "point-of-care" diagnostic tests?	Yes No Don't know	a b c
6.		In your opinion, would the introduction of bacterial or fungal "point-of-care" diagnostic testing to the general practitioner's surgery, or within the patient's own home, affect the quality of your health care?	Definitely yes Yes No Definitely no Don't know	a b c d e
7.		What is your opinion on the following statements:		
	a)	"Infectious disease home-testing kits are being developed that will allow people to test themselves at home without medical supervision for the presence of infectious diseases?"	Very favorable Favorable Unfavorable Very unfavorable No opinion	a b c d e
	b)	"Test-kits are being developed that will allow people to be tested at their own general practitioner's surgery for the presence of infectious diseases?"	Very favorable Favorable Unfavorable Very unfavorable No opinion	a b c d e
8.		If not available for free, where would you prefer to buy an infectious disease home-testing kit? (multiple choices allowed).	Your local hospital General practitioner Pharmacy Drugstore Supermarket Internet	a b c d e f

General practitioners

Q no	Labels	Question	Options
1.	a)	Do you use bacterial or fungal "point-of-care" test(s) for the diagnosis of infectious diseases at the moment?	Yes No
	b)	If yes, which type of bacterial or fungal "point-of-care" test(s) do you use? (multiple answers allowed).	Nucleic acid based Antibody based Protein based Metabolomic Don't know Other
	c)	If no, would you consider using an infectious disease "point-of-care" test in your practice in the future?	Yes No Perhaps Don't know

(Continued)

General practitioners (Continued)

Q no	Labels	Question	Options
2.		In your opinion, what are the most important factors with respect to bacterial or fungal “point-of-care” testing? (multiple answers allowed).	Costs Sensitivity Specificity Simplicity Reliability Time to diagnosis
3.		How specific should a bacterial or fungal “point-of-care” test be? The test should be able to distinguish between ...	Bacteria or fungi or viruses or no infection only Bacterial/fungal species Bacterial/fungal sub-species and major genetic types and clones Class of antibiotic resistance (eg, cephalosporin, aminoglycoside, fluoroquinolone, etc) Actual antibiotic resistance gene present No opinion
4.		Please rank the following infectious diseases where you think bacterial or fungal “point-of-care” test(s) would be particularly useful at the present moment in time.	Respiratory/gastrointestinal/sexually transmitted diseases/ urinary tract infections/woundcare/oral infections/hospital acquired infections/blood culture infections Absolutely necessary/probably useful/not useful/no opinion
5.		What would be the maximum useful “time to diagnosis” for an bacterial or fungal “point-of-care” test?	0 minutes to 5 minutes 6 minutes to 15 minutes 16 minutes to 30 minutes 31 minutes to 60 minutes 1 to 2 hours 2 to 5 hours >5 hours
6.		Complexity: in your opinion, what is the maximum number of processing steps that should be performed when using a bacterial or fungal “point-of-care” test?	1 step 2 steps 3 steps 4 steps >4 steps
7.		What in your opinion should be the current maximum cost per test for a bacterial or fungal “point-of-care” test (in euro)?	€ 0,- per test € 1,- to € 5,- per test € 6,- to € 10,- per test € 11,- to € 25,- per test € 26,- to € 50,- per test € 51,- to € 100,- per test >€ 100,- per test
8.		What is your opinion on the introduction of bacterial or fungal “point-of-care” diagnostic testing to the general practitioner’s surgery?	Very favorable Favorable Unfavorable Very unfavorable No opinion
9.		What would be your opinion if bacterial or fungal “point-of-care” diagnostic testing became available within the patient’s own home (with patients able to perform their own diagnostic testing)?	Very favorable Favorable Unfavorable Very unfavorable No opinion
10.		Do you think that home-testing using bacterial or fungal “point-of-care” testing technologies will:	
	a)	Allow you to better monitor your patients’ health?	Yes No Don’t know
	b)	Allow patients to better monitor their health?	Yes No Don’t know

(Continued)

General practitioners (Continued)

Q no	Labels	Question	Options
	c)	Increase or decrease the number of visits patients make to their general practitioner?	Greatly increase Increase Decrease Greatly decrease Have no effect Don't know
	d)	Impact on the doctor-patient relationship?	Yes (in a positive context) Yes (in a negative context) No Don't know
11.		Do you think that there will be significant problems in interpreting the results of bacterial or fungal "point-of-care" diagnostic tests?	Yes No Don't know
12.		In your opinion, would the introduction of bacterial or fungal "point-of-care" diagnostic testing to the general practitioner's surgery, or within the patient's own home, affect the quality of patient care?	Definitely yes Yes No Definitely no Don't know
13.	a)	What is your opinion on the following statements: "Infectious disease home-testing kits are being developed that will allow people to test themselves at home without medical supervision for the presence of infectious diseases?"	Very favorable Favorable Unfavorable Very unfavorable No opinion
	b)	"Test-kits are being developed that will allow people to be tested at their own general practitioner's surgery for the presence of infectious diseases?"	Very favorable Favorable Unfavorable Very unfavorable No opinion
14.		Do you believe that the use of bacterial and fungal point-of-care test(s) will positively or negatively affect how patients view your profession?	Very positively Positively Negatively Very negatively Don't know No effect
15.	a)	Do you believe that the use of bacterial and fungal point-of-care test(s) will positively or negatively affect: Your health budget?	Very positively Positively Negatively Very negatively No change Don't know
	b)	The number of patient visits you receive?	Very positively Positively Negatively Very negatively No change Don't know

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