BMJ Open Prevalence of foot disease and risk factors in general inpatient populations: a systematic review and meta-analysis

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ABSTRACT

Objective: To systematically review studies reporting the prevalence in general adult inpatient populations of foot disease disorders (foot wounds, foot infections, collective 'foot disease') and risk factors (peripheral arterial disease (PAD), peripheral neuropathy (PN), foot deformity).

Methods: A systematic review of studies published between 1980 and 2013 was undertaken using electronic databases (MEDLINE, EMBASE and CINAHL). Keywords and synonyms relating to prevalence, inpatients, foot disease disorders and risk factors were used. Studies reporting foot disease or risk factor prevalence data in general inpatient populations were included. Included study's reference lists and citations were searched and experts consulted to identify additional relevant studies. 2 authors, blinded to each other, assessed the methodological quality of included studies. Applicable data were extracted by 1 author and checked by a second author. Prevalence proportions and SEs were calculated for all included studies. Pooled prevalence estimates were calculated using random-effects models where 3 eligible studies were available.

Results: Of the 4972 studies initially identified. 78 studies reporting 84 different cohorts (total 60 231 517 participants) were included. Foot disease prevalence included: foot wounds 0.01-13.5% (70 cohorts), foot infections 0.05-6.4% (7 cohorts), collective foot disease 0.2-11.9% (12 cohorts). Risk factor prevalence included: PAD 0.01-36.0% (10 cohorts), PN 0.003-2.8% (6 cohorts), foot deformity was not reported. Pooled prevalence estimates were only able to be calculated for pressure ulcer-related foot wounds 4.6% (95% CI 3.7% to 5.4%)), diabetesrelated foot wounds 2.4% (1.5% to 3.4%), diabetes-related foot infections 3.4% (0.2% to 6.5%), diabetes-related foot disease 4.7% (0.3% to 9.2%). Heterogeneity was high in all pooled estimates $(1^2=94.2-97.8\%, p<0.001).$

Conclusions: This review found high heterogeneity, yet suggests foot disease was present in 1 in every 20 inpatients and a major risk factor in 1 in 3 inpatients. These findings are likely an underestimate and more robust studies are required to provide more precise estimates.

Strengths and limitations of this study

- This is the first systematic review and meta-analysis to investigate the prevalence of foot disease in general inpatient populations.
- A broad search strategy was used to minimise the risk of missing relevant studies.
- One author extracted data; however, this was checked by a second author.
- Studies reporting foot disease and risk factor prevalence in inpatient populations had high heterogeneity and thus pooled estimates should be interpreted with caution.
- Very few studies reported foot disease or risk factor data as the primary study outcome and most are likely to have under-reported.

INTRODUCTION

Foot disease is a common result of the pathophysiology of chronic conditions. ^{1–6} Foot disease disorders have been reported to be present in significant numbers of people hospitalised throughout the world. ^{1–6} The presence of foot disease disorders in those hospitalised has also been associated with extended hospital stays, ^{1–5} amputations, ^{1–3} 6–9 institutionalisation, ¹⁰ 11 high mortality rates ^{1 2 7 12} and significant ongoing healthcare needs. ^{1 2 6 13 14}

Foot disease is a term typically used to denote severe foot-related disorders that are likely to result in hospitalisation and amputation and most commonly refers to foot wounds and foot infections. However, 'foot disease' is also commonly used as a catchall term that collectively includes foot wounds, foot infection and other less common severe foot-related disorders, such as critical ischaemia, and Charcot neuroarthropathy. The major risk factors for foot disease include peripheral arterial disease (PAD), peripheral neuropathy (PN) and foot deformity. However, these risk factors can also become foot disease

Studies investigating the presence of foot disease in hospital inpatients have predominantly focused within discrete inpatient populations, such as only geriatric or patients with diabetes. 1 2 5 11 14 20 22 23 Fewer studies have reported the prevalence of foot disease across more representative general inpatient populations that include the diverse range of people typically hospitalised at any one time. 4 24 Thus, precise estimates of the prevalence of foot disease in general inpatient populations are unknown.4 24 Furthermore, there have been no known systematic reviews investigating the prevalence of foot disease in inpatient populations. In order for clinicians, researchers and policymakers to begin to quantify, understand and address the burden that foot disease imposes on inpatient care, it seems necessary to determine the foot disease prevalence in general inpatient populations rather than discrete segments of the inpatient population.

The primary aim of this study was to systematically review all studies reporting the prevalence in general adult inpatient populations of foot disease disorders (foot wounds, foot infections and collective 'foot disease') and risk factors (PAD, PN and foot deformity). Secondary aims were to determine the pooled prevalence estimates for each foot disease disorder and risk factor, and investigate the prevalence of amputations from included studies.

METHODS

The authors have adhered to the PRISMA guideline reporting checklist (see online supplementary table S1) and PRISMA flow diagram (see figure 1).²⁵

Search strategy

(MEDLINE, **EMBASE** Electronic databases CINAHL) were systematically searched by the first author (PAL) for all studies published between 1980 and 2013 reporting the prevalence of foot disease disorders or risk factors in an inpatient population. The year 1980 was chosen due to the advent of validated outcome measures to investigate foot disease disorders at this time.²⁶ The search strategy included broad keywords and synonyms combining the anatomical area (eg, foot); disease (eg, wounds, infection) or risk factors (eg, PAD, PN); populations (eg. inpatients); and epidemiological terms (eg, prevalence) of interest. See online supplementary table S2 for the full search syntax with truncation used for the electronic database search.

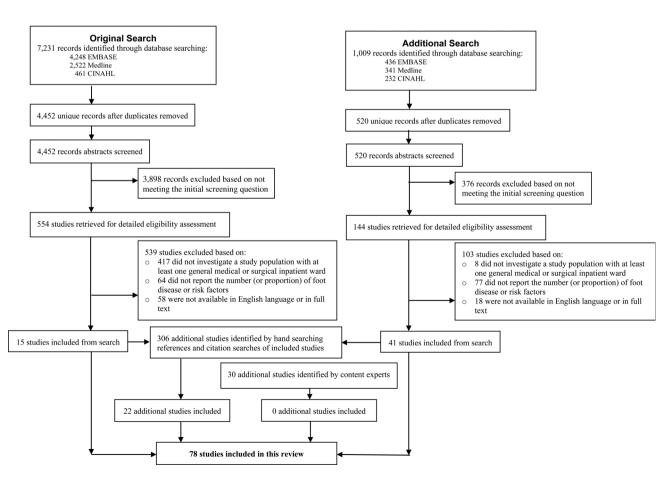


Figure 1 Search strategy and study selection results.

All unique study abstracts identified were screened by the first author (PAL) using an overarching initial screening question: Does the article appear to discuss original findings on the prevalence of foot disease or risk factors within adult populations staying overnight in a hospital? The full text was sought if it appeared to address the screening question.

A detailed eligibility assessment was then undertaken by the first author (PAL) for final inclusion. Studies were eligible for inclusion if they met all of the below inclusion criteria and did not meet any exclusion criteria. Inclusion criteria were studies:

- Indexed in the aforementioned electronic databases;
- Published in peer-reviewed academic journals;
- Available in full text;
- Written in the English language;
- Reporting a study population representative of a general adult inpatient population. General adult inpatient populations were defined as reporting all eligible participants from at least one general medical or surgical hospital inpatient ward; and
- Reporting the number, or proportion, of a foot disease disorder or risk factor. Foot disease disorders (foot wound, foot infection or collective 'foot disease') and risk factors (PAD, PN or foot deformity) were defined as listing of the foot disease disorder or risk factor concerned (or a synonym) in the study. Thus, no specific diagnostic criteria were used and reporting could have been elicited from a range of self-report, medical record audit or clinical examination methods. 'Foot disease' was defined as the collective reporting of foot wounds, foot infections and other severe foot-related disorders together.

However, studies were excluded if they met any of the following exclusion criteria:

- ▶ Studies reporting designs that were primarily case studies, literature reviews, case-control, validity or reliability studies; and
- Studies reporting a study population that was not defined as representative of a general adult hospital inpatient population; including studies investigating primarily children (<18 years), outpatients, geriatric inpatients (>65 years), long-term care inpatients or discrete condition-related inpatients (such as only patients with diabetes).

At completion of the search strategy and study selection, the first author (PAL) hand searched the reference lists of all included studies and citation searched (Scopus) all studies citing the included studies. Following this process it became apparent that all relevant studies had been identified, with the notable exception of pressure ulcers on very specific anatomical locations of the foot, such as the heel or ankle. Thus, an additional search was conducted for all studies reporting only the prevalence of pressure ulcers in inpatient populations using a similar search strategy (see online supplementary table S2). The hand searching of references lists and citation search process was repeated for any additional identified included studies from this additional search. Lastly, the authors consulted six external content experts (eg, physicians, surgeons, nurses, podiatrists) in the field. The authors forwarded the systematic review abstract, search terms and a list of all identified included studies to the content experts, and content experts provided any additional study titles they considered may have also met the inclusion criteria.

Quality assessment

Quality assessment
A study quality assessment tool was used to perform the study quality assessments of all included studies. This tool was originally designed to assess the methodological quality of pressure ulcer prevalence in inpatient populations.²⁸ The authors made minor modifications to this tool to reflect the focus of foot disease rather than pressure ulcers. See online supplementary table S3 for the modified 10-item questions used to evaluate the methodological quality of studies included in this review. Each item was scored either as a 'yes' (score=1) or 'no/not reported' (score=0) with a total possible score of 10.²⁸

Two authors (PAL and MEF), blinded to each other's assessments, assessed the methodological quality of all included studies using the aforementioned tool. A research assistant independent of the authors redacted all identifying features (title, authors and journal details) of all included studies prior to forwarding studies in a random order to the authors individually for assessment. At the conclusion of this process, the overall agreement between the two blinded author's scores was calculated and reported for all items. Any differences in the original blinded assessments between the two authors (PAL and MEF) were then resolved by consensus agreement between the two authors. A third author (SEH) was used to make a final adjudication if agreement could not be reached. Studies were given a total study quality score which was classified as either 'poor' (total score=0-3), 'moderate' (total score=4-6) or 'good' (total score=7–10) study quality.

Data extraction

Data extraction was completed for each included study by the first author (PAL) using a custom-designed data extraction spreadsheet. Data were extracted for total sample size, average age (mean or median), age range, proportion of males, and any numbers or prevalence data for the foot disease or risk factor variables. Sample size data were also extracted on condition-specific subgroups (diabetes or pressure ulcers) and amputations if reported. All extracted data were then checked for accuracy and omissions by a non-blinded second author (SDJ). At the conclusion of this data extracting checking process, the overall agreement between the second checking author's findings (SDJ) and the original author's findings (PAL) was calculated and reported. Any differences in the data extraction finding between the two authors (PAL and SDJ) were then resolved by consensus agreement between the two authors (PAL

and SDI). A third author (SEH) was used to make a final adjudication if agreement could not be reached.

Statistical analysis

Data were analysed using Stata V.13 (StataCorp LP, College Station, Texas, USA) and Microsoft Excel V.2010 (Microsoft Corporation, Redmond, Washington, USA). Descriptive statistics were reported on all included studies. Medians (IQRs) were calculated for the study quality scores of groups of studies using similar study design and reporting the same foot disease disorder or risk factor. Kruskal-Wallis and Mann-Whitney U tests were used to test study quality score differences between these groups. For the purposes of measures of agreement between authors, a percentage agreement and κ statistic were used.²⁹ The κ value (SEs) strengths of agreement were categorised as: no agreement<0; slight agreement=0-0.20; fair agreement=0.21-0.40; moderate agreement=0.41-0.6; substantial agreement= 0.61–0.8; and near-perfect agreement=0.81–1.0.²⁹

The summary statistic used for each study's foot disease disorder or risk factor variable was a prevalence proportion. The SE for each prevalence estimate was then calculated. If a study only reported numbers, these numbers were converted to a prevalence proportion using the ratio of the number of individuals with the foot disease disorder or risk factor variable reported (numerator) and the number of the total sample size of the study (denominator). Studies reporting only numbers of a foot disease disorder or risk factor per total disorder (eg, foot wounds per total wounds) were converted to numbers of patients with the foot disease disorder or risk factor for the purpose of this review. This was performed using the ratio of the number of the foot disease disorder or risk factor and the number of total disorder, multiplied by the total sample size population. These studies were excluded from any meta-analyses performed.

Meta-analyses were calculated where three or more studies of at least 'moderate' methodological quality had reported the same foot disease disorder or risk factor using a similar study design.²⁹ Meta-analyses were used to calculate pooled prevalence estimates for the foot disease disorder or risk factor using a random-effects model.²⁹ Random effects were used to give an average estimate across heterogeneous studies weighted on total sample size.²⁹ The I² test was used to test for heterogeneity across studies included in individual meta-analysis; I² values of <25%, 25-75% and >75% were rated as low, moderate and high heterogeneity, respectively.²⁹ Scatterplots were used to investigate if individual meta-analysis prevalence estimates were influenced by factors, such as sample size or study quality.²⁹

RESULTS

Search results

Figure 1 displays the search strategy and study selection results. The search strategy yielded a total of 4972 unique records of which 698 studies were retrieved for detailed eligibility assessment. Of those, 56 studies met the eligibility criteria and were included. An additional 306 potentially eligible articles were identified from hand searching references and citation searching processes from the 56 included studies and 22 of those met eligibility criteria and were included. Lastly, 30 further additional studies were identified by the external content experts and none of those met the eligibility criteria. Overall, 78 studies, reporting 84 individual hospital cohorts, were included in this systematic review.

Study characteristics

Table 1 displays the summary characteristics of the 84 individual study cohorts from the 78 included studies. Online supplementary tables S4–6 display the specific individual characteristics and citations for each of the 84 individual study cohorts. Rather than presenting tables in alphabetical order, the authors chose to group similar studies together for ease of comparison. Study cohorts were grouped according to the foot disease disorder or risk factor reported and study design (prospective or retrospective) used due to the reported prevalence differences ascertained from different foot disease disorders, risk factors and study designs.³⁰ 31

The 84 included study cohorts included a total of 60 231 517 participants; 66 (79%) prospective cohorts reported on a total of 643 141 participants and 18 (21%) retrospective cohorts reported on a total of 59 588 376 participants (table 1). Sample sizes ranged from 59 to 57 639 000, 59 to 158 236 in prospective studies and 167 to 57 539 000 in retrospective studies. Only 15 (18%) included study cohorts were investigated for foot disease disorders or risk factors as the primary aim of the study; 8 in prospective cohorts and 7 in retrospective cohorts. Study cohorts reporting foot disease disorders included: 70 (83%) foot wounds, 7 (8%) foot infection and 12 (14%) reported foot disease collectively. Study cohorts reporting risk factors included: 10 (12%) PAD, 6 (7%) PN and no studies reported foot deformity. Study cohorts could be grouped into three distinct subgroups of condition-related studies, including: 8 (10%) reporting all-cause foot disease disorders or risk factors (see online supplementary table S4), 24 (29%) reporting diabetes-related foot disease disorders or risk factors (see online supplementary table S5), and 52 (62%) reporting pressure ulcer-related foot disease disorders or risk factors (see online supplementary table S6) in their general inpatient population sample. Three studies reported both all-cause and diabetesrelated foot disease disorders or risk factor prevalence in their general inpatient population sample.

Quality assessment

Online supplementary table S7 displays the original methodological quality assessments from the two blinded authors for the 78 included studies. The κ (SE) values calculated between the two blinded author's

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2 (total possible score is 10)

Study Quality: Total agreed study quality score from the methodological assessment performed in ta

assessments ranged from 0.69 (0.10) to 0.96 (0.04) which corresponded to 'substantial' or 'near-perfect' strengths of agreement for each item analysed. The percentage agreements between the two blinded author's assessments ranged between 86% and 99% with an overall agreement of 92% (720 of the 780 total items). Table 2 displays the final agreed methodological quality assessment results for all included studies. Overall, 25 (32%) studies had 'good' methodological study quality scores, 40 (51%) had 'moderate' study quality scores and 13 (17%) had 'poor' study quality scores.

Table 1 displays differences in median study quality scores between studies reporting different study designs and different condition-related foot disease disorders or risk factors. Prospective studies reported statistically significant higher study quality scores (median (IOR) 6(5-7)) than retrospective studies (3(3-5); p<0.05). Studies reporting pressure ulcer-related foot disease or risk factors also reported statistically significant higher study quality scores (7(5-8)) than those reporting allcause foot disease or risk factors (5(4.5-6)) or diabetes foot-related foot disease or risk factors (4(3–5); (p<0.05). Table 2 displays the findings from the assessment of all 10 individual methodological quality items used. These findings revealed: 83% of studies reported a prospective design, 83% reported an appropriately sampled population, 88% recruited an adequate sample size (>300 participants), 68% used a physical examination to determine the foot disease disorder or risk factor, 67% used a validated outcome measure and 60% had an adequate response rate of eligible participants. It also revealed: only 22% reported measuring the foot disease disorder or risk factor in an unbiased manner and 0% reported foot disease or risk factor prevalence estimates with CIs.

Data extraction

Overall percentage agreement between the findings of the two authors performing data extraction was 97% (720 of the 740 total items). The 20 differences between the second author (SDJ) checking the data extraction findings of the first author (PAL) included: eight rounding, eight data entry and four case definition errors. All 20 differences were errors originally made in the data extraction process by the first author (PAL). Table 1 and online supplementary tables S4–6 display the final agreed consensus findings from the data extraction process for all included studies.

Prevalence of foot disease disorders and risk factors

Table 1 reports the total and subgroups of condition-related foot disease disorders and risk factor prevalence ranges in general inpatient populations. Total foot disease disorder prevalence ranges included: 0.01–13.5% for foot wounds, 0.05–6.4% for foot infections and 0.2–11.9% for collective foot disease. Total risk factor prevalence ranges included: 0.01–36.0% for PAD, 0.003–2.8% for PN and foot deformity was not reported.

	Study				Study	Study	Foot	Foot	Foot				
Group	cohorts (k (%))	Total San sample (n) (m)	Sample (m)	Sample range	aim k (%)	quality (M (IQR)) k	wound k (%)	infection k (%)	disease k (%)	k PA	PAD (%) k	k PN (%)	Amp (%)
Total	84 (100%)	84 (100%) 60 231 517	717 042	717 042 59–57 639 000	15 (18%)	5 (4-7)	70 0.01–13.5	0.01-13.5 7 0.05-6.4	12 0.2–11.9	10 0.	0.01-36.0 6 0.003-2.8 10 0.03-1.5	0.003-2.8	0 0.03–1.5
Prospective	(%62) 99	643 141	9745	59-158 236	8 (12%)	6 (5–7)	63 0.3-13.5	4 0.09–6.4	3 1.1–8.3	3 0.	0.2-36.0 1	1 2.80	3 0.2-1.5
Retrospective	18 (21%)	59 588 376	3 310 465	167-57 639 000	7 (39%)	3 (3–5)	7 0.01–2.3	3 0.05-0.5	9 0.2–11.9	7 0.	0.01-0.5 5	0.003-2.8	7 0.03-0.4
All-cause	8 (10%)	58 122 891	7 265 361	7 265 361 291–57 639 000	4 (50%)	5 (4.5–6)	3 0.7-4.2	2 0.09-0.5	2 0.2–1.2	4 0.	0.3-36.0	0.2	3 0.03-0.2
Prospective	4 (50%)	2471	618	291–990	2 (50%)	6 (4.5–7)	2 1.6–4.2	1 1	1 1	2 29.	29.6–36.0 –	1	1 1
Retrospective	4 (50%)	58 120 420	14 530 105	58 120 420 14 530 105 46 126-57 639 000	2 (50%)	5 (4.5–5)	1 0.7	2 0.09-0.5	2 0.2–1.2	2 0.	0.3-0.5 1	0.2	3 0.03-0.2
Diabetes-related	24 (29%)	1 965 035	81 876	81 876 167–596 591	8 (33%)	4 (3–5)	15 0.01–7.0	5 0.05-6.4	10 0.2-11.9	.0	0.01-0.4 5	5 0.003-2.8	7 0.04-1.5
Prospective	10 (42%)	15 659	1566	372-5188	3 (33%)	4 (4–5)	9 0.3–7.0	4 0.09–6.4	3 1.1–8.3	1 0.	0.2	2.8	3 0.2-1.5
Retrospective	14 (58%)	1 949 376	139 241	167-596 591	2 (36%)	3 (3-4)	6 0.01–2.3	1 0.05	7 0.2–11.9	5 0.	0.01-0.4 4	4 0.003-2.8	4 0.04-0.4
Pressure	52 (62%)	625 011	12 019	12 019 59-158 236	3 (6%)	7 (5–8)	52 0.3-13.5	1 1	1 1	 	I	1	1 1
ulcer-related													
Per person	15 (29%)	81 094	5406	5406 60-37 307	1 (7%)	7 (6–8)	15 3.0-8.5	1 1	1 1	 	I	1	1 1
Per ulcer	37 (71%)	543 917	14 700	4 700 59-158 236	2 (5%)	6 (5–7)	37 0.3-13.5	1 1	1 1	1	I	1	

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Author	Year	Question 1	Question 2	Question 3	Question 4	Question 5	Question 6	Question 7	Question 8	Question 9	Question 10	Total score†	Quality category:
All-cause													
Antonopoulos ³²	2005	0	1	1	1	1	0	0	0	1	1	6	Moderate
Currie ²⁴	1998	1	0	0	1	0	0	1	0	1	1	5	Moderate
Donnan ³³	2000	1	0	0	1	0	0	1	0	1	1	5	Moderate
Gottrup ³⁴	2013	1	1	0	1	0	0	0	0	0	0	3	Poor
Gruen ³⁵	1997	1	1	1	1	0	0	1	0	0	1	6	Moderate
Henke ³⁶	2005	1	0	0	1	0	0	1	0	1	0	4	Moderate
Lacroix ³⁷	2008	1	1	1	0	1	1	1	0	1	1	8	Good
Morgan ³⁸	2010	1	0	0	1	0	0	1	0	1	1	5	Moderate
Diabetes-related		·	, in the second	, in the second second	·			·		·	·	· ·	
Ajayi ³⁹	2009	0	0	0	1	0	0	1	0	0	1	3	Poor
Asumanu ⁴⁰	2010	0	1	1	1	1	Ö	Ö	0	1	0	5	Moderate
Chijioke ⁴¹	2010	0	0	Ö	1	0	0	1	0	1	0	3	Poor
Daultry ⁴²	2010	1	1	1	1	0	0	0	0	0	0	4	Moderate
Hurd ⁴³	2009	1	1	1	1	1	0	1	0	0	0	6	Moderate
Leichter ⁴⁴		•	0	0	1	•		1					
Mahe ⁴⁵	1982	0	0	1		0	0	1	0	0	0	2	Poor
	2006	•	1	•	1	0	0	•	0	0	1	6	Moderate
Masson ⁴⁶	1992	1	1	0	1	0	0	1	0	0	0	4	Moderate
Mohammad Akther ⁴⁷	2011	0	1	1	1	1	0	0	0	1	0	5	Moderate
Mottini ⁴⁸	2003	0	0	0	1	0	0	1	0	0	0	2	Poor
Nason ⁴⁹	2013	1	0	0	1	0	0	1	0	0	0	3	Poor
Ogbera ⁵⁰	2006	1	0	0	1	0	0	1	0	0	0	3	Poor
Ogbera ⁵¹	2007	0	1	0	1	0	0	1	0	0	1	4	Moderate
Otu ⁵²	2013	0	0	0	1	1	0	1	0	1	0	4	Moderate
Sjoberg ⁵³	2007	0	0	0	1	0	0	1	0	0	1	3	Poor
Tait ⁵⁴	2007	1	1	0	1	0	0	0	0	0	0	3	Poor
Unachukwu ⁵⁵	2007	0	1	1	1	1	Ö	0	0	0	Ö	4	Moderate
Wallymahmed ⁵⁶	2005	1	1	0	1	0	0	1	0	0	0	4	Moderate
Williams ⁵⁷	1985	1	0	0	1	0	0	1	0	0	0	3	Poor
Pressure ulcer-relate		•	Ŭ	· ·	•	Ŭ	Ŭ	•	Ŭ	Ŭ	Ŭ	Ŭ	1 001
Alja'afreh ⁵⁸	2013	0	1	1	0	0	0	0	0	0	0	2	Poor
Allcock ⁵⁹	1994	1	1	1	1	0	0	1	0	0	0	5	Moderate
Amlung ⁶⁰	2001	1	1	1	1	1	0	0	0	0	0	5	Moderate
Barczak ⁶¹		1	1	1	1	1	0	0	0	0	1	5 6	
Barrois ⁶²	1997	•	1	0			~	~		-			Moderate
	1995	1	1	~			0	0	0	0		5	Moderate
Barrois ⁶³	2008	1	1	0	1	1	0	•	0	1	1	7	Good
Bours ⁶⁴	1999	1	1	1	1	1]	0	0	0	1	7	Good
Bours ⁶⁵	2002	1	1	1	1	1	1	0	0	0	1	7	Good
Brito ⁶⁶	2013	1	1	1	1	1	0	0	0	0	1	6	Moderate
Charlier ⁶⁷	2001	1	1	1	0	0	0	1	0	0	1	5	Moderate
Clark ⁶⁸	1992	1	1	0	1	1	0	1	0	0	0	5	Moderate
Cole ⁶⁹	2004	1	1	1	0	1	0	1	0	0	0	5	Moderate
da Silva	2010	1	1	1	1	1	0	0	0	0	0	5	Moderate
Cardoso ⁷⁰													

Table 2 Continued

Author

Dealey⁷¹

Dealey⁷²

Galvan-

Gethin⁷⁷

Gosnell⁷⁸

Groeneveld⁷⁹

Gunningberg⁸⁰

Martinez⁷⁵ Gawron⁷⁶

Gallagher⁷⁴

Question

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Year

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score†

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6

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8

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8

8

Quality

Poor

Poor

Good

Good

Good

Good

Good

Good

Good

category‡

Moderate

Question

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0

Gunningberg ⁸¹	2006	1	1	1	1	1	1	1	0	0	1	8	Good
Gunningberg ⁸²	2008	1	1	1	1	1	1	1	0	0	1	8	Good
Gunningberg ⁸³	2013	1	1	1	1	1	0	0	0	0	1	6	Moderat
Hopkins ⁸⁴	2000	1	1	1	1	1	0	0	0	0	0	5	Moderat
House ⁸⁵	2011	1	1	1	0	1	0	0	0	0	0	4	Moderat
Inan ⁸⁶	2012	1	1	1	1	1	0	1	0	1	1	8	Good
Jenkins ⁸⁷	2010	1	1	1	1	1	0	0	0	0	0	5	Moderat
Lahmann ⁸⁸	2006	1	1	1	1	1	0	1	0	0	1	7	Good
Langemo ⁸⁹	1990	1	1	1	0	1	0	0	0	0	0	4	Moderat
Lepisto ⁹⁰	2001	1	1	1	0	1	0	0	0	0	0	4	Moderat
Meehan ⁹¹	1990	1	1	1	1	1	0	0	0	1	0	6	Moderat
Meehan ⁹²	1994	1	1	1	1	1	0	0	0	1	0	6	Moderat
Nyquist ⁹³	1987	1	1	1	1	1	0	0	0	0	0	5	Moderat
O'Brien ⁹⁴	1998	1	1	1	1	1	0	0	0	0	0	5	Moderat
Pearson ⁹⁵	2000	1	1	1	1	1	0	1	0	0	0	6	Moderat
Soldevilla ⁹⁶	2006	1	1	0	1	1	0	1	0	0	0	5	Moderat
Thoroddsen ⁹⁷	1999	0	1	0	1	1	1	1	0	0	1	6	Moderat
Tubaishat ⁹⁸	2011	1	1	1	1	1	1	1	0	0	1	8	Good
Tubaishat ⁹⁹	2013	1	1	1	0	1	1	1	0	0	1	7	Good
Uzun ¹⁰⁰	2007	1	1	1	1	1	0	1	0	1	1	8	Good
Vanderwee ¹⁰¹	2007	1	1	1	1	1	1	0	0	0	1	7	Good
Vanderwee ¹⁰²	2011	1	1	1	1	1	1	0	0	1	1	8	Good
Vangilder ⁴	2008	1	1	1	1	1	0	0	0	1	1	7	Good
Vangilder ¹⁰³	2010	1	1	1	1	1	0	0	0	1	1	7	Good
Wann-	2008	1	1	1	1	1	0	1	0	1	1	8	Good
Hansson ¹⁰⁴													
Whittington ¹⁰⁵	2004	1	1	1	1	0	0	0	0	0	0	4	Moderat
Young ¹⁰⁶	2002	1	1	1	1	1	1	1	0	0	1	8	Good
Zhao ¹⁰⁷	2010	1	1	1	1	1	0	1	0	0	1	7	Good
Total (n)		65	65	53	69	52	17	46	0	20	39	426	
Total (%)		83.3	83.3	67.9	88.5	66.7	21.8	60.0	0	25.6	50.0	54.6	

Amputation prevalence ranges were 0.03–1.5%. The prevalence ranges were different for subgroups of condition-related foot disease disorders and risk factors reported. Prevalence ranges for foot wounds included: 0.7-4.2% for all-cause foot wounds; 0.01-7.0% for diabetes-related foot wounds and 0.3-13.5% for pressure ulcer-related foot wounds. Prevalence ranges for foot infections included: 0.09-0.5% for all-cause foot infection, 0.05-6.4% for diabetes-related foot infections and pressure ulcer-related foot infections was not reported. Prevalence ranges for collective foot disease included: 0.2-1.2\% for all-cause foot disease, 0.2-11.9\% for diabetes-related foot disease and pressure ulcer-related foot infections was not reported. Prevalence ranges for PAD included: 0.3-36.0% for all-cause PAD and 0.01-0.4% for diabetes-related PAD. Prevalence ranges for PN included: 0.2% for all-cause PN and 0.003-2.8% for diabetes-related PN. Again prevalence was greater in prospectively designed studies for all condition-related foot disease or risk factors investigated in general inpatient populations, with the exception of collective foot disease and PN.

Meta-analyses

Four foot disease disorders met the prespecified minimum for meta-analysis calculation of three eligible studies with similar study designs. Tables 3-6 report the pooled prevalence estimates from the meta-analyses calculations for pressure ulcer-related foot wounds, diabetes-related foot wounds, diabetes-related foot infections and diabetes-related foot disease. Table 3 reports a pooled prevalence estimate for pressure ulcer-related foot wounds based on 14 included studies reporting sample sizes ranging from 60 to 37 307 and study quality scores from 4 to 8. The pooled prevalence estimate was 4.6% (95% CI 3.7% to 5.4%, p<0.001; $I^2=95.3\%$,

p<0.001). Examination of scatterplots revealed a bias between higher reported pressure ulcer-related foot wound prevalence and those studies using an unbiased, reliable outcome measure (figure S1).

Table 4 reports a pooled prevalence estimate for diabetes-related foot wounds based on six included studies reporting sample sizes ranging from 624 to 5188 and study quality scores from 4 to 6. The pooled prevalence estimate was 2.4% (95% CI 1.5% to 3.4%, p<0.001; I^2 =94.2%, p<0.001). Examination of scatterplots revealed sources of bias between higher reported diabetes-related foot wound prevalence and those studies either reporting smaller sample sizes, having lower study quality or I^2 =94.2%, p<0.001). Examination of scatterplots revealed studies conducted in developing countries (figure S2).

Table 5 reports a pooled prevalence estimate for diabetes-related foot infections based on three included studies reporting sample sizes ranging from 827 to 5188 and study quality scores from 4 to 5. The pooled prevalence estimate was 3.4% (95% CI 0.2% to 6.5%, p<0.05; I^2 =97.0%, p<0.001). Scatterplots were not evaluated due to the limited number of included studies.

Table 6 reports a pooled prevalence estimate for diabetes-related foot disease based on three included studies reporting sample sizes ranging from 810 to 5188 and study quality scores from 4 to 5. The pooled prevalence estimate was 4.7% (95% CI 0.3% to 9.2%, p<0.05; I^2 =97.8%, p<0.001). Scatterplots were not evaluated due to the limited number of included studies.

DISCUSSION **Principal findings**

This study is the first systematic review to investigate the prevalence of foot disease in representative general inpatient populations. The prevalence of foot disease disorders in general inpatient populations ranged from

	Sai	mple Prev	alence	Percentage	Study
Table 3	Pooled random-effects estil	imates for <i>pressure</i>	ulcer-related foot wour	d prevalence expressed as	% (95% CI)

	Sample	Prevalence		Percentage	Study quality
Study	size	estimates	95% CI	weighting	score
Barrois <i>et al⁶³</i>	37 307	3.7	3.5 to 3.9	9.86	7
Brito <i>et al⁶⁶</i>	473	4.7	2.8 to 6.5	6.59	6
Gallagher <i>et al</i> ⁷⁴	672	3.0	1.7 to 4.3	8.05	8
Gethin <i>et al</i> ⁷⁷	506	3.0	1.5 to 4.4	7.59	7
Gunningberg ⁸⁰	612	8.8	6.8 to 11.4	5.89	8
Gunningberg ⁸¹	369	4.6	2.5 to 6.7	6.04	8
Gunningberg and Stotts ⁸²	632	6.5	4.6 to 8.4	6.53	8
Gunningberg <i>et al⁶³</i>	16 466	6.7	6.3 to 7.1	9.71	6
House <i>et al⁶⁵</i>	60	5.0	-0.5 to 10.5	1.88	4
Lahmann <i>et al⁶⁸</i>	16 728	3.2	2.9 to 3.5	9.81	7
Tubaishat <i>et al</i> ⁹⁸	302	7.8	4.7 to 10.9	4.29	8
Tubaishat and Aljezawi ⁹⁹	295	3.0	1.1 to 4.9	6.54	7
Vanderwee <i>et al</i> ¹⁰¹	5947	4.4	3.9 to 4.9	9.55	7
Wann-Hansson <i>et al</i> ¹⁰⁴	535	3.0	1.5 to 4.4	7.67	8
Pooled estimate		4.6	3.7 to 5.4	p<0.001	
<u>l²</u>		95.3%		p<0.001	

0% to 13%, while the prevalence of a major risk factor for foot disease ranged from 0% to 36%. Meta-analyses could only be calculated for four condition-related foot disease disorders. These pooled prevalence estimates indicated that 4.6% (95% CI 3.7% to 5.4%) of all inpatients had a pressure ulcer present on their foot, 4.7% (0.3% to 9.2%) had collective diabetes-related foot disease, 2.4% (1.5% to 3.4%) had diabetes-related foot wounds and 3.4% (0.2% to 6.5%) had diabetes-related foot infections. Additional findings from this review suggested up to 1.2% of all inpatients had been hospitalised for the primary reason of foot disease. However, this systematic review also revealed large variations in reported prevalence and study quality within each foot disease disorder or risk factor of interest. These variations appear to have been the major contributors to the high statis-

tical heterogeneity reported in the pooled prevalence

Strengths and weaknesses

estimates from this review.

The findings of this systematic review should be viewed in the context of several consistent limitations observed in the included studies of this review. First, most included studies reported foot disease disorders or risk factor as an additional outcome and no included studies reported CIs or sample size calculations for foot disease findings. Second, most included studies reported a condition-related (such as diabetes-related), rather than an all-cause, foot disease disorder or risk factors in a general inpatient population. Third, study quality scores varied considerably depending on the study design and foot disease disorder or risk factor investigated. Fourth, all-cause and diabetes-related foot disease disorder or

risk factor findings were predominately reported from retrospective studies. Lastly, while studies reporting pressure ulcer-related foot disease were all prospective and mostly of high quality, a large proportion reported only pressure ulcers on the heel. Overall, these limitations impact on the capture, precision and heterogeneity of findings and indicate included studies are likely to have under-reported foot disease disorder and risk factor prevalence.

The authors are also cognisant of limitations in the methodology used to perform this systematic review. First, this review used broad inclusion criteria for foot disease disorders, risk factors and general inpatient population definitions, and this may have contributed to the heterogeneity of findings. Second, the original search strategy was performed by only one author and did not initially identify studies reporting pressure ulcerrelated foot wounds on specific anatomical locations of the foot. However, the authors believe this was addressed by conducting a broad initial search strategy, an extensive additional pressure ulcer-related search strategy, hand searching references of all included studies, citation searching all included studies and contacting external content experts to identify any remaining relevant studies. Third, only one author extracted data. However, a second author checked all data extraction finding and reported very high percentage agreement with the original data extraction findings. Fourth, the tool used to assess the methodological quality of included studies had not been tested for reliability and validity. However, the tool reported substantial interrater reliability agreement between blinded authors in this study, had high face validity and aligned with items

		Sample	Prevalence	Percentage	Stu
Table 5	Pooled random-effects	estimates for	diabetes-related foot infe	$\it ction$ prevalence expressed as $\%$ (95	% CI)

Study	Sample size	Prevalence estimates	95% CI	Percentage weighting	Study quality score
Asumanu <i>et al</i> ⁴⁰	966	3.3	2.2 to 4.4	33.42	5
Mohammad Akther <i>et al</i> ⁴⁷	5188	0.6	0.4 to 0.8	34.82	5
Unachukwu <i>et al⁵⁵</i>	827	6.4	4.7 to 8.1	31.76	4
Pooled estimate		3.4	0.2 to 6.5	p=0.037	
<u>l</u> ²		97.0%		p<0.001	
<u>-</u>		37.078		ρ<0.001	

Table 6 Pooled random-effe	cts estimates for	diabetes-related foot	disease prevalence	e expressed as % (9	5% CI)
Study	Sample size	Prevalence estimates	95% CI	Percentage weighting	Study quality score
Asumanu <i>et al</i> ⁴⁰	966	8.3	6.6 to 10.0	32.66	5
Daultrey et al ⁴²	810	4.9	3.4 to 6.4	33.05	4
Mohammad Akther et af ⁴⁷	5188	1.1	0.8 to 1.3	34.28	5
Pooled estimate		4.7	0.3 to 9.2	p=0.038	
I^2		97.8%		p<0.001	

reported to provide best practice methodological quality assessments for observational studies. Lastly, the pooled prevalence estimates calculated in this review reported very high statistical heterogeneity, and some may argue the value of reporting such heterogeneous findings. However, the authors used conservative random-effects meta-analyses models weighted on total sample size in an attempt to account for heterogeneity. Furthermore, the authors consider the reporting of heterogeneous pooled prevalence estimates, with the clear cautionary notes provided by the authors on interpretation, provide considerable additional value and transparency to the existing literature available in this field. Page 1998.

Interpretations of findings

The most consistent deficiency in study quality identified in this review was that no studies reported CIs for foot disease or risk factor prevalence findings. This was most probably related to very few studies investigating a foot disease disorder or risk factor as their primary outcome of interest. 24 32 36 37 41 42 47 49 50 52 83 106 107 Most studies reported foot disease or risk factors as an additional aim to the primary study aim of investigating the prevalence of a larger condition, such as the total pressure ulcer or diabetes prevalence. This lack of focus on foot disease may have led to an under-reporting of prevalence findings as suggested in other similar studies.⁵ 30 31 Furthermore, 7 of the 15 study cohorts that were investigated primarily for a foot disease disorder or risk factor were retrospective studies. 24 36 49 50 52 Retrospective studies have been found to also considerably underreport prevalence compared with prospectively designed studies utilising validated outcome measures,^{5 30 31} and this also seemed to be the case in this review. Only eight study cohorts were prospectively investigated for the primary reason of identifying a foot disease disorder or risk factor; ³² ³⁷ ⁴⁰ ⁴² ⁴⁷ ⁸³ ¹⁰⁶ ¹⁰⁷ however, only one used an unbiased method of measurement.³⁷ This particular study investigated PAD using a reliable and validated non-invasive ankle brachial index method.³⁷ With nearly all studies either retrospective in design or investigating a foot disease disorder or risk factor as an additional outcome, it could be hypothesised that the pooled prevalence estimates reported in this review are likely to underestimate the actual burden of foot disease in inpatient populations.

Foot wounds were by far the most identified and reported foot disease disorder arising from this systematic review. Yet, only three studies reported on all-cause foot wound prevalence. 24 34 35 A large retrospective study by Currie *et al*²⁴ investigating foot disease disorders and risk factors when they were the primary reason for admission was the only study with the primary aim of investigating all-cause foot wounds and reported a foot wound prevalence of 0.7%. The other two studies were prospective studies and reported all-cause foot wound prevalence of 1.6%³⁴ and 4.2%,³⁵ respectively. However, the primary aims of these prospective studies were to investigate wound prevalence, and thus, identifying foot wounds was one of several additional aims investigating different wound locations. 34 35 Limitations in study numbers and quality calls into question the precision of all-cause foot wound prevalence estimates and meant pooled estimates could not be calculated.

In contrast, the study numbers and quality were sufficient to perform meta-analyses on diabetes-related foot wound and pressure ulcer-related foot wound prevalence. The increased numbers of studies reporting these two condition-related areas is perhaps not unexpected considering aspects of diabetes and pressure ulcer management are commonly utilised internationally as key performance indicators of hospital care quality.⁴ 109-112 Foot wounds are major contributors to poor outcomes in both these conditions. 4 38 63 101 110 The pooled prevalence estimates for diabetes-related foot wounds (2.4%) and pressure ulcer-related foot wounds (4.6%) from this review indicate these foot wounds do contribute considerable burdens on the hospital inpatient system. While there were more studies investigating these two condition-related foot wounds in general inpatient populations again both pooled prevalence estimates had very high heterogeneity. This may be attributed to only 'moderate' study quality scores being eligible for inclusion in **@** the calculation of the diabetes-related foot wound pooled prevalence estimate. However, this was not the case for the pressure ulcer-related foot wound pooled prevalence estimate where overall included study quality scores were 'good'. Interestingly, the only factor identified in the scatterplots to bias pressure ulcer-related foot wound prevalence findings was the bias of the investigators themselves. This suggests in studies where investigators or data collectors investigated participants from their own hospitals pressure ulcer prevalence were

under-reported. As this was the only factor identified to bias pressure ulcer-related foot wound prevalence from this review, it is therefore plausible, that the variation in pressure ulcer-related foot wound prevalence is largely affected by the quality of care provided by the individual hospital. Thus, this would support the ongoing use of unbiased pressure ulcer prevalence as a key performance indicator of hospital care quality.⁴ 82 101

It was apparent that most studies reporting pressure ulcer-related foot wounds did not exclude wounds of diabetes origin, and conversely, most studies reporting diabetes-related foot wounds did not exclude wounds of pressure ulcer-related origin. This potential crosscontamination suggests studies reporting pressure ulcerrelated foot wounds may inadvertently be a combination of the prevalence of pressure ulcer-related and diabetesrelated foot wounds. Furthermore, literature reports stage 1 pressure ulcers make up to 50% of the total pressure ulcer burden. 63 82 101 Stage 1 pressure ulcers are defined as non-blanchable erythema without skin loss or a 'pre-pressure ulcer'. 63 82 This suggests the real pressure ulcer-related foot wound prevalence in those inpatients with skin loss may make up only 50% of the 4.6% pooled prevalence estimate reported from this review. Thus, it could be hypothesised that the real pressure ulcer-related wound prevalence may be closer to 2.4% pooled prevalence estimate findings for diabetes-related foot wounds. Again considering the high likelihood of cross-contamination of these two large condition-related foot wound types, this hypothesis may extend to the suggestion that pressure ulcer-related foot wounds with skin loss could be a useful surrogate marker for all-cause foot wound prevalence and a potential indicator of foot care quality. However, these hypotheses need to be interpreted with much caution until further investigations support its use in this capacity.

Foot infection was the other major foot disease disorder included in this review and was typically reported to affect existing foot wounds. 47 51 55 The retrospective analysis by Currie et $a\ell^{24}$ was the only study primarily investigating all-cause foot infection prevalence and reported a rate of 0.5%. Another retrospective study to primarily investigate foot infection reported a rate of 0.1%; however, this study only investigated foot osteomyelitis (bone infection).³⁶ The remaining five cohorts reported diabetes-related foot infections.² The prospective pooled prevalence estimate for diabetesrelated foot infection was 3.4% (0.2–6.5); yet, statistical heterogeneity was again high and needs to be interpreted with caution. This is particularly the case considering pooled prevalence estimate for diabetes-related foot infection was higher than for diabetes-related foot wounds. However, the findings from the three studies used to calculate the diabetesrelated foot infection pooled prevalence estimate each individually found higher diabetes-related foot wound prevalence than they did for diabetes-related foot infection prevalence. 40 47 55

The aforementioned study by Currie et al^{24} was also the only study to primarily investigate all-cause collective foot disease prevalence in a general inpatient population. This retrospective study analysed the proportion of foot disease that were the primary reason for admission from over 300 000 hospitalisations recorded in a Welsh national hospital discharge data set.²⁴ Interestingly, even though the retrospective study design used in this large study make significant under-reporting likely,⁵ ³⁰ ³¹ it still identified that collectively foot disease was the primary reason for admission in 1.2% of hospitalisations.²⁴ Foot disease was also collectively reported in 11 other study cohorts with prevalence ranging from 0.2% to 11.9%. However, a pooled $4.7\%^{40}$ 43 45 47 51 55 prevalence estimate could only be calculated for diabetes-related foot disease and this was again a heterogeneous finding. One factor that may have influenced these high heterogeneous findings was the different synonyms and inclusion criteria used to define collective foot disease disorders between studies. The terms varied between 'foot disease', 40 'foot problems', 42 53 'diabetic foot'38 41 and an aggregation of different foot disease disorders. 24 47 49 The inconsistency of terms, definitions and the specific foot disease disorders included within these collective 'foot disease' groups appears to be a major contributing factor in the heterogeneity of these findings. It is recommended that a formal international consensus process is undertaken to determine an agreed foot disease definition so as to allow clinicians and researchers to compare homogeneous 'foot disease' outcomes in future.

The major risk factors for foot disease included in this study were PAD, PN and foot deformity. PAD was the most reported risk factor in 10 cohorts. 'moderate-to-good' quality prospective studies of allcause PAD using similar gold standard non-invasive vascular outcome measures reported similar 29.6% and 36.0% prevalence findings. 32 37 In contrast, other PAD studies were either retrospective in design or reported PAD using a non-valid or reliable method. However, the methodological deficiencies of these studies translated to poorer study quality scores and much lower PAD prevalence ranges of 0.01-0.5%. Thus, using the most robust study quality evidence available, it could be hypothesised that PAD is present in approximately one-third of general inpatient populations.³² ³⁷ PN was reported in six cohorts with the only study reporting all-cause PN prevalence (0.2%) again the retrospective **Q** study by Currie et al.²⁴ All other studies reported diabetes-related PN prevalence ranging from 0.003% to 2.8% in general inpatient populations. ²⁴ ⁴⁰ ⁴⁴ ⁴⁸ ⁵² The only study to primarily investigate diabetes-related PN identified that 2.8% of all inpatients had diabetes-related PN using a validated tool. 40 However, with only one retrospective study reporting all-cause PN and all other studies reporting condition-related PN, these low reported PN prevalence rates could again be considered to under-report the actual all-cause PN prevalence in

inpatients. Foot deformity was not identified by this review. Unfortunately, there were insufficient studies of satisfactory quality to enable the calculation of a pooled prevalence estimate for any risk factor. Therefore, until further studies are conducted, the best estimate of the proportion of general inpatient populations with a major risk factor for foot disease appears to be up to 36%.³² ³⁷

Lastly, amputation prevalence was reported in 10 included study cohorts identified by this review ranging from 0.03% to 1.5%. 24 33 36 40 46 48 55 50 The only study primarily investigating all-cause amputation in this context was again the retrospective study by Currie et al²⁴ suggesting 0.1% prevalence in general inpatient populations. Most remaining studies reported diabetesrelated amputation rates which ranged between 0.04% and 1.5%. 24 33 40 46 48 55 50 Unfortunately, there were insufficient studies to calculate a pooled prevalence estimate. However, this prevalence range may not be exhaustive and needs to be interpreted with caution, as amputation was a secondary aim of this review and only reported from studies that also reported foot disease or risk factors.

Implications for clinicians, researchers and policymakers

While reviews have been investigating the inpatient burden of major organ disease for some time, such as heart disease, ^{113–115} this appears to be the first review to determine more precise estimates for foot disease in general inpatient populations. This review has identified that foot disease is present in considerable proportions of the general inpatient population. Primary findings indicate 1 in 20 inpatients had foot disease and 1 in 3 inpatients had a major risk factor for foot disease. This review also supports existing evidence suggesting foot disease is present in large proportions of discrete inpatient populations, such as patients with diabetes¹⁻³ and pressure ulcers. 4 82 101 Furthermore, additional findings indicate 1 in every 100 inpatients had been hospitalised because of foot disease and up to 1.5% of all inpatients were in hospital to have an amputation procedure. Although pooled prevalence estimates in this review had high heterogeneity, they are the most precise prevalence estimates to date to quantify the burden of foot disease present in general inpatient populations. Overall findings from this review appear to be very likely an underestimate of this burden.

With such a considerable proportion of foot disease present in inpatient populations, it is perhaps surprising that more research has not been conducted to primarily this potentially considerable investigate However, this review does highlight the need for clinicians, researchers and policymakers to better understand and address this seemingly under-recognised burden in inpatient populations. It is recommended that future studies in this field should be prospective in design, have a primary aim to investigate foot disease in inpatient populations and use unbiased, reliable and

validated foot disease and risk factor outcome measures. Furthermore, it is recommended the findings of this review should inform policy to more precisely address this under-recognised yet considerable burden of foot disease in inpatient populations.

CONCLUSIONS

This is the first known systematic review to synthesise the literature on foot disease in inpatient populations and provides the best estimates to date of this burden. Findings from this review indicate up to 36% of all inpatients had a major risk factor for foot disease, 5% had foot disease and up to 1% were in hospital because of foot disease. Owing to the high heterogeneity of included studies, these estimates need to be interpreted with caution; however, they are more likely to underreport the inpatient foot disease burden. This review highlights the urgent need for further research to more robustly quantify, and address, what appears to be a considerable burden of foot disease present in general inpatient populations.

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