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エビデンスに基づく日本の保健医療制度の実証的分析

平成 26-28 年度　総合研究報告書

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II 章

総合研究報告

厚生労働科学研究費補助金（地球規模保健課題推進研究事業）
「エビデンスに基づく日本の保健医療制度の実証的分析」（H26-地球規模-一般-001）

総合研究報告書

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研究要旨
UHC（すべての人が基本的な保健サービスを支払い可能な価格で享受できること）が大きな政策目標となったグローバルヘルス分野において、我が国の知見がアジア諸国を中心とした発展途上国から求められている。また、低成長と少子高齢化の中で多くの課題が噴出し、我が国がどのように対応していくかが世界の注目を集めている。本研究は、WHO の Asia-Pacific Health Observatory（APO）「Health Systems in Transition (HIT)」の枠組みを活用し、我が国の保健医療制度の現状と課題及び将来像を、実証的かつ包括的に分析することを主な目的としている。より具体的には、１）我が国の保健医療の組織とガバナンス、２）保健医療財政、３）人的資源、４）サービス供給体制、５）医療改革および６）都道府県間における健康格差についての系統的レビューを実施した。過去３年間にわたる本研究の成果を十分に反映したものとなるようドラフトの改定を行い、HIT レポートの最終稿を完成することができ、今秋には WHO から出版の予定である。これらの研究から得られた知見は、UHC を達成した日本の足跡をたどる開発途上国が、社会経済状況や疾病構造の変化とそれが保健医療政策に及ぼす影響についての対処を講じるために広く活用されることが期待される 。

Ａ．研究目的

世界保健機関（WHO）の保健医療制度比較の枠組みを用いた近年の我が国の保健医療制度の包括的分析としては、多田羅・岡本らによる「Health Systems in Transition (HIT)」(2009 年)レポート、渋谷・橋本らによる「英ランセット誌日本特集号」（2011 年）がある。UHC（全ての人に基本的な保健サービスを支払い可能な価格で普及させること）が大きな政策目標となったグローバルヘルス分野において、我が国の知見がアジアを中心とした発展途上国から求められている。また、低成長と少子高齢化の中で多くの課題が噴出し、我が国がどのように対応して行くかが世界の注目を集めている。

本研究は上記２つの包括的分析を行った研究チームが共同で研究を実施し、WHO の Asia Pacific Observatory on Health Systems and Policies (APO)との連携のもと、HIT の枠組みを利用し、我が国の保健医療制度の現状と課題、そして将来像を実証的かつ包括的に分析し、グローバルヘルスにおける政策に資することを主な目的とする。本研究は、HIT と 2000 年度版「世界保健報告：保健システムパフォーマンス」の保健制度パフォーマンス分析の枠組みに則り実施された。

具体的には、１）我が国の保健医療の組織とガバナンス、２）保健医療財政、３）人的資源、４）サービス供給体制、５）医療改革および６）都道府県間における健康格差についての系統的レビューを行う。

The Asia Pacific Observatory on health systems and policies (APO) では、西太平洋地域における諸外国がユニバーサル・ヘルス・カバレッジ（UHC）（全ての人が基本的な保健サービスを支払い可能な価格で享受できること）を達成し、医療制度再建に関わる経験を共有することを目的として、Health Systems in Transition（HIT）レポートを刊行している。本プロジェクトでは 2009 年に日本における HIT レポートが刊行されているが、今回研究では最新結果を踏まえ HIT レポートの更新も行う。

Ｂ．研究方法

本研究では、厚生労働省、内閣府および OECD で公表済みのデータ及び厚労省二次利用申請済みデータを用いて、日本の保健システムに関するレビュー並びに分析を実施した。

<u>我が国における健康とリスク</u>

1980-2012 年における日本と OECD 加盟国の経済変化や人口推移、および主要な保健衛生上の指標に関するデータを Global Burden of Disease プロジェクトが公表している特定疾患の負荷に関するデータと併せて統合した。統合データに対して、1995 年以降の保健支出パターンの解析を実施した。統合データは、ヘルスケアの種類や購入販売者間の関係、支払い方法に関する資源分配を決める上での意思決定がどのように行われているかを記述する上でも活用した。

<u>2000 年および 2006 年における診療報酬</u>

改定が病院の看護配置（Patient-Nurse Ratio: PNR）と平均在院日数（Length of Hospital Stay: LHS）にもたらした効果

厚労省二次利用申請済みの「病院報告」および「医療施設調査（静態）」の個票データ（1984-2008 年）を用いて、「差の差」分析（Difference-in-Difference : DID）の手法を適用して解析した。

高齢者ケアのコミュニティー組織の役割

Japan Gerontological Evaluation Study (JAGES) のデータを用いた。また、関連する国税調査および死亡率に関するデータを用いて、ヘルスケアへのアクセスおよび結果の不平等性を評価した。さらに、JAGES データを用いて、包括ケアシステム従事者のケアプラン作成、ならびにケアの質に関する基本事項実施に関する能力の評価を行った。利用データでは、ケアの質に対する満足度とケアに関するアンケート評価を実施した。

厚生労働省より利用申請を得た各種統計（2015 年 3 月許可、全詳細省略）のうち、21 世紀中高齢者縦断調査、国民生活基礎調査、介護給付費実態調査個票を用いて次年度のための予備的解析を行った。具体的には 1）介護保険制度の点数改定によるサービスへの影響、2）医療介護需要の将来推計に向けた慢性疾患の同時確率推計に向けた基礎検討、3）認知症を伴う要介護者の状況と在宅介護の課題について仮説を立て、相関解析等を実施した。

日本での健康格差

厚生労働省の統計調査データである国民健康栄養調査、国税調査ならびに国民生活基礎調査を用いて、日本での健康格差について評価した。保健の水平的公平は集中度を用いて評価し、財政破綻は復数の破綻に関する閾値を用いて評価した。女性によるインフォーマルケアのレベルに対する格差はケアの種類の違いに関するレポートを統計的に解析して評価した。

米国高齢者間の保健ケア需要予測を目的に構築された将来高齢モデル（Future Elderly Model: FEM）に基づくミクロシミュレーションモデルを開発し、高齢化を迎える日本における将来の保健ケア需要を予測した。これらの解析結果は、日本の保健財政及び包括的ケアシステムの政策実施に利用した。

C．研究結果

平成 26 年度は我が国の保健制度に関する包括的評価を実施した。評価の実施により、非感染性疾患（以下 NCDs）の増加と高齢化が日本社会に大きく影響していることが明らかになった。NCDs の負荷と高齢化は OECD 加盟国の大半でも同様に進行中であるが、日本の保健システムにおける物的・人的資源は OECD 加盟国内でも平均以下であることがわかった。GDP に占める日本の保健システムへの助成金額の比率は OECD 加盟国の多数より低いこと、また自己負担額（out of pocket: OOP）の負荷は発展途上国に比べて高いにも関わらず、健康保険の財政破綻のリスクを示す事実はないことがわかった。また、薬の

価格や支払い、長期ケアシステムに関する政策改革の必要性が明らかになった。

さらに平成 26 年度には PNR と LHS の時系列分布の解析を実施した。大・中規模の病院では 2006 年の入院基本料の値上げ改定以前から対応策を講じ、施設内の人的資源に対する意思決定を行っていたことが示唆される一方、小規模の病院では同基準を満たしている施設が 20%と少数であり、すなわち価格政策に対する弾力性は病床規模に依存していることがわかった。また、1）介護保険制度の点数改定によるサービスへの影響、2）医療介護需要の将来推計に向けた慢性疾患の同時確率推計に向けた基礎検討、3）認知症を伴う要介護者の状況と在宅介護の課題について、それぞれ解析を実施した。1)では、通所介護における利用状況の有無に大きな変化は見られなかったものの、付加サービスについては、一部サービス事業所で利用回数の増加が見られる傾向が確認された。2)では、パネル調査により心臓病、脳卒中、がんなど慢性疾患の併発率の推定を行った。欠損の処理方法に結果が著しく依存して変わることが確認されたため、本結果を足がかりに適切な処理方法の確立と推計モデル構築に向けて進める課題を明らかにした。3)では、認知症を伴う要介護者を持つ世帯は約３割であること、また要介護者は嫁・実子による介護が主であることがわかった。

世界の喫煙動向に関しては、2000 年から 2010 年にかけて、男性における喫煙率が 125 カ国（72%）、女性では 156 カ国（49%）で減少した。この傾向が継続した場合、37 カ国（21%）が男性の削減目標を達成できる見込みであることが示された。一方、アフリカでは男性、東地中海では男女ともに急激な喫煙率増加が予測され、現在の傾向が継続した場合、たばこの蔓延のリスクがあると予測された。

平成 27 年は高齢化と我が国の保健財政を中心に検証を行った。保健財政を支える歳入増加ならびに増収分の保険者への分配について、必要不可欠な方策が複数抽出された。中でも、後期高齢者の保健ケアシステムの発展は、今後３０年で最も成長が著しいと考えられる人口区分に対する保健ケア財政の持続可能性が改善されたが、今後高齢化が進むに連れ、更なる包括的ケアシステムを支える財政再建策が必要となることがわかった。高齢者ケアは、今現在、地域包括ケアシステム内で行われているが、地域包括ケアシステムに従事しているスタッフは、ケアプランやケアに対する基本次項を提供する能力に改善が見られることがわかった。また、従事者の能力改善はケアシステムの他の組織との連携も改善されていることが２年に渡る研究データの収集から明らかになった。

国民生活基礎調査のデータ解析により、自己報告型の健康に関する格差は１９９５年より相対的に変化がないこと、男女ともに格差は小さいこと、また最貧層の女性において悪化していることを示す事実が明らかになった。また、ケアに対するアクセスの格差が男女ともに低所得層で拡大

している事実も明らかになった。さらに、高校卒業よりも最終学歴が低い女性は有意にインフォーマルケアに従事していることがわかった。ケアの質およびアクセス、ならびに最貧困層家族へのケア提供に存在する格差は、高齢化が進むに連れてますます重要となってくる。

最終年度である平成 28 年度は、都道府県間における健康格差に関する分析を行った。1990 年から 2015 年の間に日本全体での平均余命は 4.2 年(79 歳から 83.2 歳)延長したが、都道府県の間でその進捗には差異があり、平均寿命の伸びが一番短い沖縄県では 3.2 年の伸長だったのに対し、滋賀では 4.8 年の伸長が見られた。同時期に都道府県間の平均余命格差(平均余命が最も長い県と最も短い県の差異)も 2.5 年から 3.1 年へと拡大を見せた。健康寿命は 1990 年の 70.4 歳から 2015 年には 73.9 歳へと延長したが、平均寿命と同様に都道府県間の格差は同時期に 2.3 年から 2.7 年へと拡大した。

1990 年から 2015 年の間で、死亡率については日本全体では 29.0%の減少が見られたが、こちらも地域格差が大きく、一番減少率が高い滋賀県では 32.4%だったのに対し、減少率が一番低い沖縄県では 22.0%だった。障害調整生存年（DALYs）、損失生存年（YLLs）、生涯生存年（YLDs）の減少率はそれぞれ 19.8%、33.4%、3.5%であったが、この結果からは総死亡に比較して若年死亡が大幅に減少したことを示唆している。上位３位の死因は 1990 年から 2015 年まで一貫して脳血管疾患、心血管疾患、呼吸器疾患となっている。これら主要死因による死亡率は 1990 年から大幅に減少したものの（各々 -19.3%、-11.6%、-6.5%の減少率）、2005 年以降は年間の減少率に男女共鈍化が見られており、さらに上位１０死因のうち、アルツハイマー病だけは唯一年齢調整死亡率の上昇が見られた。

主要死因の年齢調整死亡率は都道府県間によって差が大きく、例えば、脳血管疾患による死亡率は一番高い岩手県（10 万人当たり 62.0 人）と一番低い滋賀県（10 万人当たり 37.9 人）の間では 1.6 倍の開きがあった（10 万人当たり 37.9 人）。DALY についても都道府県間での差異を分析したところ、脳血管疾患や虚血性心疾患と行った生存を脅かし得る疾患については 47 都道府県の間で大きな違いが見られたのに対し、例えば腰痛や感覚器障害と行った、致死性ではない疾患については都道府県の間で有意差は見られなかった。

全死因のうち、47.1%は危険因子が同定可能であった：行動様式に由来するリスクが 33.7%、代謝リスクが 24.5%、環境および職業上のリスクが 6.7%であった。同様に、DALYs のうち 34.5%はリスク要因が同定可能であった。行動様式に由来するリスクのうち、主なものとして食塩摂取や喫煙習慣が挙げられるが、これら高リスク行動様式を有する割合と都道府県間の健康指標の間には優位な相関関係は見られず、先に報告した平均寿命や疾患別死亡率、DALYs の地域差を説明する結果とはならなかった。

最後に、都道府県間における健康指標格

差の要因として、各地域における医療資源の投入状況の関係（人口当たりの医療従事者数、一人当たり医療費）についても分析を行ったが、総死亡率及び DALYs のいずれについても有意差は得られなかった。

D．考察

本プロジェクトは、WHO の HIT レポートの改定のプロセスを通して、現在の「日本の保健医療制度」、「日本人の健康状態」及び「非感染性疾患（以下 NCDs）による疾病負担の増大及び高齢化社会といった政策決定者が直面する重要な課題」を体系的に評価した。また、近年行われた主な政策転換の概要及び変遷を提示し、これらが医療施設及び介護システムにもたらした影響について量的手法を用いて検証した。さらに、本研究では、高齢化と NCD による負荷が増大している中で日本の保健システムの持続可能性改善に向けた再検索の進展、ならびに再建による保健ケアの格差の評価を実施した。ケア提供とアクセスに関する継続した格差の存在は、将来の日本の保健システム再建へ示唆を与えるものである。

我が国は 1989 年から一貫して世界第 1 位の平均寿命を誇っているが（東日本大震災があった 2011 年は除く）、これは特に心血管疾患及び悪性新生物による死因が減少したことが大きい。しかしながら、2005 年を境に年齢調整死亡率・DALYs ともに減少のスピードは鈍化を見せており、「保健医療 2035」で提示されたようなパラダイムシフトが今まさに求められていると言える。

平均寿命や健康寿命の地域格差は拡大傾向にあり、先行研究でも指摘されてきた通り、北日本に行くにつれその健康指標は悪化が見られる。これは、人口動態や疾病構造の変化への対応が地域間で公平ではなかったことを示唆するものであり、今後は各都道府県の事情に合わせた医療制度の構築が求められる。このような地域格差を生む要因として、生活習慣（食塩摂取や喫煙）との関連性を分析したが有意差は得られなかった。この結果からは医療制度の差といったその他の誘因によって地域差が惹起されている可能性があるが、他方で、地域レベルにおける危険因子に関するデータが本研究では不十分だった可能性もあり、この点については今後、さらなる検証が必要である。同様に、地域レベルでの医療資源の投入（人口当たりの医療従事者数、一人当たり医療費）と健康指標の地域間格差についても分析を行ったが有意差が得られなかった。今後は、健康指標に影響を与えうるその他の社会経済的要因について分析が必要である。

全世界的に共通であるが過去 25 年の間に死亡率は大きな減少を見せた。我が国においてもその傾向は同じであるが、他方、主要死因については依然として脳血管疾患・心血管疾患・呼吸器系感染症となっている。言い換えれば、我々はこれら主要死因に対する方策をさらにスケールアップすることが必要である。同時に、政策決定プロセスの中に費用対効果の視点を取り、有用な予防手段への積極的な投資を進め

ていくことが必要である。

為政者に対して、本研究の発見から短中期的な視点で以下の３点において政策立案の提案が可能である。

- 再建策は既に実施されているが、保健医療財政の将来的な再建および統合的ケアシステムには、高齢者に低コストで高い質のケアを継続的に提供できることを保証する必要がある。
- 保健従事者は高齢化と社会保障、保健ケアシステムの継続的な統合の準備は進んでいる一方で、高齢者ケアの負荷の大部分は個人、すなわちインフォーマルケアによって担われている。もし格差の原因となっていないのであれば、このような日本の伝統的な高齢者ケアの方式は注意深く検討すべきである。
- ケアの質とアクセスに関するリスクは高齢化が進むに連れて悪化すると予想されるため、保健システムが再建注も平等であることを保証する必要がある。

なお、本プロジェクトの大部分は近年の我が国の政策の変遷を考慮に入れた HIT の枠組みに基づく HIT レポート改訂版の原案となっている。またレポートに加え、過去 10 年にわたる我が国の保健医療制度の変革から明らかになった教訓は APO を通してアジアの発展途上国と共有され、各国の UHC 達成への道しるべとなることが期待される。

特に、本プロジェクトの結果は以下の点において国及び世界地域の保健医療政策に寄与する。

- 日本の保健医療制度が直面する課題及び解決のための今後の政策転換への示唆に関する系統的な考察
- 近い将来日本と同様の疫学的課題を伴う経過を辿るであろう UHC システムが整っていないアジアの発展途上国が課題を解決するための政策戦略の提示及び共有
- 特定の価格と金融政策が保健医療制度の活用に与える効果に関する科学的知見の提供（政策決定がどのように実際の保健医療システムに影響を与えるかについて理解を深めるための日本国内及びアジア全体の基準を提示する）

Ｅ．結論

1990 年から 2015 年の間に、我が国おいては平均余命の伸長及び、死亡率・合併症の大幅な減少を見せた。しかしながら、その減少率は 2005 年以降鈍化傾向にあり、また健康指標の改善率には地域間格差があることもわかった。高齢化により、日本の保健システムが様々な課題に直面しており、安定的な財政と保健格差の不安は国際的にも周知の事実である。「保健医療 2035」で唱えられたビジョンを踏まえ大胆な制度改革が望まれるとともに、国レベルでのより一層の予防対策の強化や、地域の実情に合わせた地域毎の対策強化が今後は必要である。

F．健康危険情報

特になし

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H．知的財産権の出願・登録状況
（予定を含む。）

1. 特許取得

特になし

2. 実用新案登録

特になし

3. その他

特になし

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Ⅲ章
研究成果の刊行に関する一覧表

研究成果の刊行に関する一覧表

（2014 年 4 月 1 日～2017 年 3 月 31 日迄）

2014 年 4 月 1 日～2015 年 3 月 31 日迄

発表者氏名	論文タイトル名	発表雑誌	巻号	ページ	出版年
Noguchi H	How does the price regulation policy impact on patient-nurse rations and the length of hospital stays in Japanese hospital?	Asian Economic Policy Review	10		2015
Gilmour S, Liao Y, Bilano V, Shibuya K	Burden of disease in Japan; Using national and subnational data to inform local health policy	Journal of Preventive Medicine and Public Health	47	136-143	2014
Okamoto E	Farewell to free access: Japan’s universal health coverage	East Asian Forum	February		2014
Ueda P, Kondo N, Fujiwara T	The global economic crisis, household income and pre-adolescent overweight and underweight: a nationwide birth cohort study in Japan	International Journal of Obesity	1		2015
Bilano V. Gilmour S, et al.	Global trends and projections for tobacco use, 1990-2025: an analysis of smoking indicators from the WHO Comprehensive Information Systems for Tobacco Control.	The Lancet	385	966-976	2015
Nishino Y, Gilmour S, Shibuya K	Inequality in diabetes related hospital admissions in England	PLOS ONE	10	e0116689	2015

	by socioeconomic deprivation and ethnicity: Facility-based cross-sectional analysis.				
Saito E, Gilmour S, Rahman MM, Gautam SS, Shrestha PK, Shibuya K	Catastrophic household expenditure on health in Nepal: a cross-sectional survey	Bulletin of the World Health Organization	92	760-767	2014

2015 年 4 月 1 日～2016 年 3 月 31 日迄

Working papers

発表者氏名	論文タイトル名	出版年
橋本英樹, 岩本哲哉	介護サービス市場における供給者誘発需要仮説の検証	2016
Tokunaga M, Hashimoto H	Socioeconomic within-gender gap in informal caregiving among middle-aged women: an evidence from Japanese nationwide survey	2016
Kasajima M, Hashimoto H	Development of micro-simulation model to forecast health and wellbeing in older Japanese	2016

雑誌

発表者氏名	論文タイトル名	発表誌名	巻号	ページ	出版年
Reich M, Shibuya K	The Future of Japan's Health System – Sustaining Good Health with Equity at Low Cost	New England Journal of Medicine	373	1793 – 1797	2015

Liao Y, Gilmour S, Shibuya K	Health Insurance Coverage and Hypertension Control in China: Results from the China Health and Nutrition Survey	PLOS ONE	11	E0152091	2016
Rahman M, Abe SK, Kana M, Narita S, Rahman MS, Bilano V, Ota E, Gilmour S, Shibuya K	Maternal body mass index and risk of birth and maternal health outcomes in low- and middle-income countries: A systematic review and meta-analysis	Obesity Reviews	16	758-770	2015

2016 年 4 月 1 日～2017 年 3 月 31 日迄

発表者氏名	論文タイトル名	発表雑誌	巻号	ページ	出版年
Tokunaga M, Hashimoto H	The socioeconomic within-gender gap in informal caregiving among middle-aged women: Evidence from a Japanese nationwide survey	Social Science & Medicine	173	48-53	2017
Nomura S, Haruka S, Scott G, et al. (31 co-authors)	Slowed-down progress in population health and increasing regional variations of disease burden in Japan, 1990-2015: a systematic subnational analysis for the Global Burden of Disease Study 2015.	The Lancet			
Islam MR, Rahman MS, Islam Z, Zhang C, Sultana P, Rahman MM	Inequalities in financial risk protection in Bangladesh: an assessment of universal health coverage.	International Journal for Equity in Health	16	59	2017

How Does the Price Regulation Policy Impact on Patient-Nurse Ratios and the Length of Hospital Stays in Japanese Hospitals?

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Abstract

This study examines how the 2000 and 2006 revisions of the fee-for-service system have affected patient-nurse ratios and the average length of hospital stays in Japan. The empirical results show that hospitals are quite responsive to changes in price policy. The fee revisions have certainly achieved the policy objectives of reducing patient-nurse ratios and the length of hospital stays. As a result, hospitals have responded by greatly increasing the number of expensive beds for acute care. However, this was not exactly predicted by the Japanese government which has aimed to reallocate health care resources such as beds to sub-acute or long-term care.

Key words: price regulation, fee-for-service (FFS) system, patient-nurse ratio, length of hospital stay, natural experiment, kernel propensity score matching difference-in-difference estimation

JEL codes: I11, I18

1. Introduction

The Japanese health care system has seemed to be functioning successfully during the last several decades. This would be implied by the fact that Japan has achieved the highest level of population health in the world at a relatively low cost (WHO, 2000; Hashimoto et al., 2011)[2]. However, some statistics show that the financial stability of the health care system in Japan will be under threat, in particular, from demographic and economic factors in the future (Shibuya *et al.*, 2011). The population aged 65 and older will continue to increase from 33.952 million in 2015 to 36.573 million in 2025 when the baby boomers become 75 years of age and older, and then it will be peak at 38.782 million in 2042 (NIPSSR, 2013). On the other hand, the working-age population (those aged 15-64) which supports the current pay-as-you-go social security system will shrink from 76.818 million in 2015 to 70.845 million in 2025, and then to 55.985 million in 2042 (NIPSSR, 2013). Among the OECD countries, the recent rate of increase in total health expenditure as a percentage of gross domestic product (GDP) was the largest in Japan, an increase of 2 percentage points from 8 % in 2005 to 10% in the 2010s (OECD, 2014)[3]. Further, the outstanding stock of Japanese national debt mainly caused by the growth of social security expenditure was 10.46 trillion US dollars in 2013, which is more than double the size of GDP (about 4.9 trillion US dollars), and it is the biggest public financial burden in the world (Schwartz, 2013). In order to make the universal health care system financially

[2] Japan's global health indices, such as life expectancy at birth (79.9 years for males and 86.4 years for females), infant mortality (2.2 deaths per 1,000 live births) and perinatal mortality (2.9 deaths per 1,000 live births), are among the best in the world, while its total health expenditure as a percentage of gross domestic product (GDP) was 10% in 2011, ranking 23th among the OECD countries where data are available in 2011-2013 (OECD, 2014; MHLW, 2010).

[3] During the same period, total health expenditures as a percentage of GDP increased by approximately 1.7 percentage points in Korea, the United States, and New Zealand, 1.3 percentage points in Canada, 1.2 percentage points in Spain and Ireland; and 1.1 percentage points in Denmark, the United Kingdom, and the Netherlands.

sustainable given the drastic changes in population structure and severe budget constraints, health care reform which moves towards a more efficient reallocation of both physical and human resources is urgently required.

Economic theory explains how an equilibrium price is achieved through the market mechanism, which makes the distribution of resources efficient, yet does not necessarily lead to equity in the society. However, in Japan, medical care is reimbursed under a nation-wide uniform single payment system mainly based on a fee-for-service (FFS) system completely controlled by the government. FFS is paid equally, regardless of the types of insurance[4] and facility[5]. It is worth noting that Japan's FFS is not adjusted to take account of regional cost differences (Ikegami & Anderson, 2012). After an overall revision rate for medical care services as a whole is determined by negotiations between the Ministry of Health, Labour and Welfare (MHLW) and the Ministry of Finance[6], the FFS is officially revised on an item-by-item basis every other year through discussions among the representatives of various interest groups (for example, physicians,

[4] Since the Japanese public health insurance became a compulsory system in 1961, people are forced to be enrolled into one of five types of public health insurance: (1) the "National Health Insurance (NHI)" for farmers, self-employed, and retired persons under the employee's health insurance; (2) health insurance for the employees of large firms and managed by health insurance societies; and for the employees of small firms and managed by the Japan Health Insurance Association (*Zenkoku Kenko Hoken Kyokai*); (3) health insurance for the employees of national and local governments, and teachers or the staff of private schools and managed by mutual aid associations; (4) seamen's insurance; and (5) the medical care system for people aged 75 and older.

[5] The Japanese Medical Service Law defines two types of medical facilities, hospitals and clinics. A "hospital" is a medical facility with 20 or more beds, while a "clinic" has less than 20 beds or no beds at all.

[6] The overall revision rates for the FFS set in these negotiations have apparently been influenced by changes in political power. Under Prime Minister Junichiro Koizumi, the overall revision rates were set at 0 or negative levels, such as -1.30% in 2002, 0.00% in 2004, and -1.36% in 2006, because the Liberal Demographic Party (LDP) regarded achieving positive primary balance by 2011 as the first priority of fiscal policy and, therefore, the LDP attempted to suppress social security spending. After the Democratic Party of Japan (DPJ) won the election in 2009, the overall revision rates have turned positive, for example, 1.55% in 2010 and 1.38% in 2012, which reflected the DPJ's policy of enhancing social security services rather than suppressing the financial deficit. The latest revision rate of 0.63% is slightly positive and will be offset by an increase in the consumption tax rate from 5% to 8% implemented at the same time of the revision in April 2014, after the LDP regained government.

pharmacists, dentists, psychiatrists from the supply-side, insurers, and patients from the demand-side, and public interest groups as a third party) at the Central Social Insurance Medical Council appointed by the MHLW[7]. Price regulation of medical care services imposed by the government would influence the economic welfare in society, through the effects of the revisions of the FFS on medical care providers' treatment choices and, consequently, the allocation of medical care resources. Hence, it is important for policy makers to evaluate the impacts of a change in price policy on supply-side behavior (Tokita, 2004).

Some researchers emphasize the primary contribution of the reimbursement system described earlier as being cost containment and, therefore, the efficiency in providing medical care up to now (Ikegami & Campbell, 2004; Wagstaff, 2005; Ikegami et al. 2011; Ikegami & Anderson, 2012). These points are also indicated in a report by the MHLW as being important characteristics of the current health care system[8]. In contrast, other empirical studies in the economics field using micro-based individual data have reached different conclusions. First, the supply of medical care would often be inefficient because supplier-induced demand (SID) might deliver unnecessary care for improving patient outcomes, due to the asymmetric information among patients, insurers, and medical care providers (Evans, 1974; Fuchs, 1978; Pauly, 1980; McGuire, 2000). As has been found in the United States, some earlier studies have found the presence of SID in Japanese medical care (Kawai & Maruyama, 2000; Tokita, 2004; Suzuki, 2005; Shigeoka & Fushimi, 2014). These studies deal with either the introduction of the Diagnosis

[7] For details of the process of revising the FFS, see Hashimoto et al. (2011), Ikegami and Campbell (2004) and MHLW (2012).

[8] In addition to providing high-quality medical care at relatively low cost, MHLW (2015) characterizes the Japanese health care system as follows: compulsory universal coverage as of 1961; free access to medical care without a gatekeeping system; and income-related social insurance subsidized by general taxes.

Procedure Combination (DPC) or the Prospective Payment System (PPS) in 2003 (Kawai & Maruyama, 2000; Shigeoka & Fushimi, 2014), or the revision of the FFS in every other year (Tokita, 2004; Suzuki, 2005) as natural experiments[9] and evaluate the impacts of changes in price policy on medical care providers' treatment choices and/or patterns. In sum, the results show that medical care providers were quite responsive to the DPC/PPS adoption and/or the revision of FFS, in the sense that they might extend the length of hospital stays, increase the frequency of visits to a medical facility, and raise even patient-days, in order to compensate for the decrease in the unit price of medical care[10].

Second and more importantly, the Japanese regulated price policy could lead to a more uneven distribution of medical care resources with respect to geographic regions and clinical departments or specialties. To my knowledge, Iizuka and Watanabe (2014) is the first empirical study to tackle this issue, using the introduction of the New Postgraduate Medical Education Program in Japan in 2004 as a natural experiment, in order to clarify the differences between the short-run and long-run demands for physicians in the labor market. Hospitals in rural areas often have to pay physicians much higher salaries than hospitals in urban areas in order to attract physicians. But, the price-regulation policy does not allow these medical facilities to raise their fees for patients and absorb higher wages, so that they have to exit the market in the long-run. Therefore, Iizuka and Watanabe (2014) conclude that "the demand for physician labor is inelastic in the short-run but more elastic in the long-run". Nevertheless, Iizuka and Watanabe (2014) could

[9] As of 2003, the Japanese government introduced a new-flat-fee payment system called the DPC or PPS, which covers part of inpatient hospital care. For the differences of this Japan's version of the case-mix payments and Diagnosis-Related Groups (DRGs), please see Ikegami and Anderson (2012).
[10] Some researchers argue that SID might not occur or that the size of SID could be small enough to be ignored in Japan, since most physicians are employees so that they might have no incentive to induce demand. In addition, by law there are no private hospitals for-profit in Japan (Kishida, 2001; Kadoya & Kodera, 2014).

not isolate the effect of price regulation on the labor supply of physicians directly, because the price policy, more specifically, the revisions of the FFS, influence all over the medical care market and, therefore, a control group which is not affected by the revisions could not be identified. This is one of the most critical challenges for empirical studies attempting to evaluate the impacts of price policy in Japan.

This study focuses on another key human resource for medical care, nurses, because the patient-nurse ratio (PNR) in a ward has been one of the most significant factors for determining reimbursements under the FFS system in the past few decades. For example, it is internationally well-known that the average length of a hospital stay (LHS) is much longer in Japan than in other OECD countries (OECD, 2014)[11], and that this has been considered to be one of the major causes of rising medical expenditures. Ogata (2003) indicates that the insufficient allocation of medical care professionals such as physicians and nurses in acute care hospitals would make LHS longer in Japan than in other developed countries[12]. Therefore, the FFS system raised the reimbursement rate for hospitals with a PNR less than a certain standard, conditional on shortening LHS. Unfortunately, for the same reason as in Iizuka and Watanabe (2014), so far, no studies have clarified the impact of the revisions of the FFS on the demand and supply in the labor market for nurses without a relevant counterfactual. Hence, the main objective of this study is to examine the effects of price regulation on PNR in a ward and the average LHS, using the FFS revisions as natural experiments. There are five types of inpatient

[11] The average LHS in Japan for all causes has decreased rapidly from 34.4 days to 17.5 days during the 1994-2012 period. This would be caused by the separation of hospital beds for long-term care from beds for acute care in August, 2008. Even so, LHS in Japan still remains much longer than the OECD average of 7.4 days.

[12] Ogata (2003) also stated that the larger number of hospital beds per 1,000 people compared to other countries and the mixture of inpatients with acute and chronical diseases in the same wards are major causes of the longer LHS in Japan.

beds for (1) psychiatric disease, (2) infectious diseases, (3) tuberculosis, (4) long-term care, and (5) other, called general beds. The reimbursement varies by type of beds[13]. Since the major revisions of FFS have been attempting to the PNR and the average LHS of general beds, this study pays attention to only hospitals that have general beds.

In the next section, I describe some background information for this study. Section 3 explains the data used and the econometric strategy. The empirical results are presented in the Section 4, and the final section contains a conclusion.

2. Background

2.1 Nurse labor market in Japan

The insufficient number of nurses in Japan has often been discussed in the past few decades[14]. In response to an increase in the demand for nursing care in hospitals caused by population aging and the diffusion of high-tech care (MHLW, 2012), the number of universities with schools of nursing and, therefore, the total quota of nursing places at universities have been growing rapidly following the Act on Assurance of Work Forces enacted in 1992 by the Ministry of Education, Culture, Sports, Science and Technology (MEXT)[15]. This has contributed to an increase in the total supply of nurses, such that the

[13] In 2010, the numbers of beds by type of bed are: 346,715 for psychiatric disease, 1,788 for infectious diseases, 8,244 for tuberculosis, 332,986 for long-term care, and 903,621 for other. Accessed 19 January 2015. Available from URL: http://www.mhlw.go.jp/toukei/saikin/hw/iryosd/11/dl/1-2.pdf

[14] In accordance with the Economic Partnership Agreements (EPA) that Japan has signed with Indonesia, the Philippines, and Vietnam, the Japanese MHLW has been accepting trainees for nursing and long-term care workers from these countries since 2008. In the seven years from 2008 to 2014, the total number of accepted trainees for nursing was 839. However, of these trainees, only 128 of them passed the National Nursing Examination, which is not enough to influence the entire nurse labor market in Japan, although the percentage of these trainees who pass the exam has increased from 0% in 2008 to 10.6% in 2013. Accessed 19 January 2015. Available URL: http://www.mhlw.go.jp/file/06-Seisakujouhou-11650000-Shokugyouanteikyokuhakenyukiroudoutaisakubu/epa_gaiyou.pdf

[15] The number of universities with a school of nursing has increased from 14 in 1992 to 210 in 2013. Accordingly, the quota on the number of nursing places in universities rose greatly from 748 to 17,779

number of registered nurses (RNs) has rapid increased from 308,415 in the mid-1980s to 1,015,744 in 2012, an increase of about 9 percentage on average every year. Accordingly, the total number of nurses has more than doubled from 590,177 in 1984 to 1,373,521 in 2012, although the number of licensed practicing nurses (LPNs) has declined since 2000[16][17]. Thus, as Figure 1 indicates, compared to other OECD countries, the number of practicing nurses per 1,000 population is not so low in Japan. In 2010, the number of practicing nurses per 1,000 Japanese population was about 10, which is higher than the average of 34 OECD countries which was 8.8.

[Figure 1 around here]

Even though the total labor supply of nurses has been growing, on average, the effective job openings to applications ratio has always been more than 1.0, and even this ratio has grown from 1.18 in 2000 to 2.69 in 2013 (MHLW, 2014). This indicates that excess demand still remains. An answer from a macro perspective might be the geographically uneven distribution of nursing labor. The allocation of nurses is biased toward the south-west regions, and urban areas such as Tokyo and Osaka seem to have an insufficient

during the same period. MEXT. Table for trend of number of universities and quotas with school of nursing and Quota (*in Japanese*). Accessed 19 January 2015. Available from URL: http://www.mext.go.jp/component/a_menu/education/detail/__icsFiles/afieldfile/2014/01/20/1314031_3.pdf

[16] In Japan, RNs are required to have 3,000 or more hours of training in a nursing program in universities, colleges, or professional schools and to pass the National Nursing Examination in order to obtain a license. On the other hand, LPNs should have 1890 or more hours of training in professional schools or 5-years consecutive nursing high-school and pass a qualification exam conducted by any of the 47 prefecture-level governments. According to the current rapid development of medical technology, further sophisticated expertise and higher-tech skills are required to provide nursing care in medical facilities. Hence, the abolition of LPNs has been one of major debates among interest groups, such as Japanese Nursing Association (JNA) and Japan Medical Association (JMA) (JNA, 2009).

[17] The number of physicians also started increasing in the mid-1980s by about 4 percentage on average every year. However, the number of nurses has increased much faster than the number of physicians.

number of nurses, even though this is where acute care hospitals are concentrated and so the demand for nursing care is relatively high.

From a micro perspective, Nakata and Miyazaki (2010) provide another possible reason for this. First, they suspect that the national health reform in 1994 increased the demand for nurses, because supplemental care by family members for inpatients was no longer be allowed in hospitals and nurses' aides were excluded from the nominal head count of nursing staff used in calculating the daily reimbursements as of 1994. Therefore, the reform motivated hospitals to hire more RNs and LPNs in order to maintain the levels of PNR and so, reimbursements, which would lead to a rise in the demand for nurses. Second, Nakata and Miyazaki also discussed that nurses' wages have not increased much, despite the tight labor market, contrary to the standard demand-supply theory. Figure 2 shows the mean hourly wages of nurses and their wages relative to the wages of welfare service workers from 2001-2013. Overall, the mean hourly wage has not changed so much and has even slightly fallen in some periods, while the relative wages of RNs and LPNs compared to welfare worker have been increasing, but not considerably. Thus, it might lessen an individual nurse's incentive to stay in the labor market, due to their low opportunity costs for a heavy workload. Therefore, the policy implications suggested by Nakata and Miyazaki (2010) are: to introduce a reorientation program for nurses who are no longer in the labor market; to restructure the working environment for nurses; and finally, to reassess the current wage system.

[Figure 2 around here]

2.2 **Major revisions of the FFS related to the nurse labor market**

This section describes the major revisions of the FFS for inpatient hospital care which might influence the labor market for nurses in the last three decades, focusing on the PNR for general beds. Figure 3 shows the trend in PNR by hospital size[18] and the timing of major revisions of the FFS.

[Figure 3 around here]

As of 1988, a ward where an employed nurse is assigned to ten inpatients (the so-called 10:1 PNR) and the average LHS is less than 20 days, started to be reimbursed with an additional payment[19]. After 1988, the nurse placement in medium-sized hospitals had been catching up rapidly with that in large hospitals, where a relatively low PNR had already achieved before the revision. Then, the FFS for wards not meeting the legal standard of PNR required by the Medical Care Act, which is twenty patients per employed nurse (20:1 PNR), was abolished in 1992 and hospitals which did not meet this standard could no longer be reimbursed by the FFS system. Further, as discussed in the previous section, the national health reform in 1994 forbid supplemental care by family members for inpatients and, after the reform, nurses' aides have no longer been counted in the PNR for the purpose of calculating the daily reimbursement as of 1994. The major revisions in 1992 and 1994 should have led to a fall in the PNR even in small hospitals speedily. As

[18] Hospitals are categorized into three sizes, small hospitals (the number of general beds is less than 100), medium-sized hospitals (the number of general beds is 100 and more and less than 500), and large hospitals (the number of general beds is 500 and more), and these categories are generally utilized in the surveys conducted by MHLW.

[19] In this study, the PNRs are shown are based on the new standard revised as of 2006. Before 2006, each PNR of "7:1", "10:1", "13:1", "15:1", "18:1", and "20:1" were counted as "1.4:1", "2:1", "2.5:1", "3:1", "3.5:1", and "4:1" (Nagata et al., 2012). Please see footnote 27 for a further explanation.

of 2000, three categories of charges for nursing care, medical supervision and management, and a hospital room were combined into an inpatient hospital fee[20]. Also, as conditions for additional reimbursements, the average LHS for various standards of PNRs were revised to 21 days or less for "10:1"; 26 day or less for "13:1"; 60 days or less for "15:1"; and 90 days or less for "18:1", respectively (MHLW, 2012). Finally, a new standard for inpatient hospital fees was introduced in 2006. Nagata et al. (2012) provide a good summary for this as follows. Instead of the number of inpatients per employed nurses, the number of inpatients per working nurses per working hour became a new criterion as of 2006[21]. Also, as a new criterion for an additional reimbursement, a PNR of "7:1" conditional on average LHS of 19 days or less (so-called a "7:1" hospital) was introduced by the FFS system.

[Figures 4 & 5 around here]

Figures 4 and 5 summarize the trend of the number and distribution ratio of general beds in 1984-2008, by hospital size and types of hospital based on criteria for an additional reimbursement defined in 2000 and 2006. The total number of general beds which meets the standard of a "7:1" hospital defined by the FFS system in 2006 were 1,354 (9% of total number of general beds), which has been increased to 317,901 in 2008 (43%). The increase could be clarified by increasing the number of general beds of the

[20] Under the FFS system, dietary therapy expenses started to be evaluated separately from patient inpatient hospital fees as of 2000 (MHLW, 2012).

[21] Nagata et al. (2012) provide an example as follows, "if there were 20 nurses assigned to a ward with 40 patients, according to the previous standard it was calculated that there was one nurse for every 2 patients (=2:1). On the other hand, if there are 20 nurses assigned to a ward, at most only 4 nurses can work at same time because of shift work; therefore, by the new standard it was calculated that 40:4 = 10:1".

"7:1" type in medium-sized and large hospitals, while the number of beds of the "non-7:1" type in both sized hospitals has been decreasing gradually after 2000 (Figure 4). Also, Figure 5 shows that almost all medium-sized and large hospitals could meet the conditions for additional reimbursements after 2000, but more than 30% of small hospitals have not satisfied with these standards, and they have remained categorized into "other". Even so, regardless of hospital size, the distribution ratios of general beds which meet the standard of additional reimbursements have been increasing rapidly, in particular, after 2000. In sum, these simple basic statistics indicate how hospitals started to respond especially to the FFS revisions as of 2000. Therefore, among the revisions of the FFS in the past decades, this study focuses on the latest drastic revisions of inpatient hospital fees in 2000 and 2006 as natural experiments when the FFS system begun to clarify new standards based on PNR combined with LHS for an additional reimbursement. The data and econometric strategy are explained in the next section.

3. Data and Econometric Strategy

3.1 Data structure

This study constructs hospital-year-based data by combining data from two nation-wide surveys conducted by the MHLW, the "Hospital Report (HR)", and the "Survey of Medical Institutions (SMI)", which contain common hospital identifiers from survey to survey.

Both HR and SMI are population surveys which cover the entire hospital system in Japan. First, the HR contains two questionnaires, one regarding patients and the other relating to employees [22]. Each hospital has to submit the results of the patient

[22] All clinics with inpatient beds have to provide answers only to the questionnaire for patients every month (Accessed 19 January 2015. Available URL: http://www.mhlw.go.jp/toukei/list/80-

questionnaire which includes the total numbers of inpatients and discharged patients every month to the MHLW, while the questionnaire for employees is conducted once a year on the 1st of October and asks about the number of physicians, RNs, LPNs, dentists, pharmacists, and other type of employees.

Unfortunately, in these surveys, the data necessary to calculate the new criteria adopted from 2006, such as working hours and the structure of the shifts of nurses, is not available. Instead, I simply define a PNR for a hospital in year *t* as follows:

$$\mathrm{PNR_t} = \frac{\sum_{j=1}^{12} total\ number\ of\ inpatients\ in\ jth\ month\ of\ year\ t\ /12}{Number\ of\ RNs\ on\ Oct\ 1\ of\ year\ t} \qquad (1)$$

where t=1984, …, 2008.

Second, SMI is conducted once every three years on the 1st of October[23][24]. As with HR, SMI includes questions related to the type and number of inpatient beds and employees, and it has more detailed information on facilities compared to HR, such as the type of owners, the presence of clinical departments, emergency rooms, an intensive care unit (ICU), cardiac ICU (CICU), pediatric ICU (PICU), and teaching/educational systems. Out of these, I use only variables commonly available from 1984 through 2008[25].

1a.html#link01), but clinics with no beds do not need to report answers to the HR. In order to focus on the supply of inpatient care service in hospitals, this study excludes the data for clinics with inpatient beds.

[23] Therefore, the data are available in 1984, 1990, 1993, 1996, 1999, 2002, 2005, and 2008.

[24] There is also a vital survey in the SMI, which is a monthly report related solely to the opening and closing of hospitals/clinics (Accessed 19 January 2015. Available URL:http://www.mhlw.go.jp/toukei/list/79-1b.html#1). This study uses only hospital data in the static survey of SMI.

[25] Details of the number of inpatient beds, the type of owner, the presence of teaching/educational systems, and the population size of municipality where a hospital is located are available for every period. But, details of the type of owners and the presence of teaching/educational systems are included only in SMI, but not in HR. So, for these variables, assuming that they do change over the three year period, I merged HR with SMI.

Finally, HR and SMI are merged by using the common hospital identifier in each survey year. This study excludes hospitals which do not have general beds or which do not meet any criteria of both PNRs and LHS for additional reimbursements as of 2000 described in section 2.2[26]. The average LHS seem to be too long for these hospitals, probably because HR does not clarify the number of inpatients by type of beds so that the average LHS including patients with non-acute diseases might be evaluated.

3.2. Econometric strategy

The econometric strategy used in this study is simple and straightforward. For the primary purpose of this study – evaluating how responsive and sensitive hospitals are to a change in price policy-, we visually want to show a change in PNR and LHS, before and after the revision of the FFS system. I apply a difference-in-difference (DID) estimator on the common support with kernel propensity score matching before/after the revisions of FFS system in 2000 and 2006, respectively. As described in the previous section, the revisions provide distinct criteria for the PNR combined with LHS for an additional reimbursement, so that control and treatment groups can easily be constructed in a DID context. An advantage of the use of a kernel propensity score matching DID estimation method is that we can ignore observable time-invariant effects on PNR and LHS because the model is supposed to extract hospitals which have similar characteristics either in the treatment or the control group[27]. For reference, our final model is as follows.

[26] Hospitals which are categorized into "Other" in Figure 5 are excluded from the regression analyses.
[27] However, endogeneity issues still remain because it is difficult to make adjustments for time-variant unobservable hospital characteristics. I will discuss this in the last section.

$$\hat{\delta} = \frac{1}{N_{\text{after}}} \sum_{i \in I_{\text{after},1}} \left(Y_{\text{after},i}(1) - \sum_{j \in I_{\text{after},0}} W\left(P\left(X_{\text{after},i}\right), P\left(X_{\text{after},j}\right)\right) Y_{\text{after},j}(0) \right) -$$

$$\frac{1}{N_{\text{before}}} \sum_{i \in I_{\text{befpre},1}} \left(Y_{\text{before},i}(1) - \sum_{j \in I_{\text{before},0}} W\left(P\left(X_{\text{before},i}\right), P\left(X_{\text{before},j}\right)\right) Y_{\text{before},j}(0) \right) \quad (2)$$

where [before] and [after] implies post- and pre-revision of the FFS in 2000 and 2006. Then, hospitals which have satisfied the new standard for an additional reimbursement, a PNR of "7:1" conditional on average LHS of 19 days or less before the year of 2000/2006 are defined as "the controlled" (control group) and those which have not achieved "7:1" requirements before 2000/2006 as "the treated" (treatment group). [$I_{\text{after},1}$,$I_{\text{before},1}$] and [$I_{\text{after},0}$,$I_{\text{before},0}$] are respectively the treatment and control groups before and after 2000 and 2006, respectively, and N_t [t=after, before] is the number of hospitals in the treatment group. Let D_i be a dummy variable indicating the i^{th} hospital's status with $D_i = 1$ indicating a "non-7:1" hospitals and $D_i = 0$ indicating a "7:1" hospital. The variables indicating the i^{th} hospital's PNR and LHS are denoted by $Y_{t,i}(D_i)$ as a function of D_i. $P\left(X_{\text{t},i}\right)$ is the propensity score for the i^{th} hospital at time t. The variables appearing in $X_{\text{t},i}$ are dummy variables relating to the i^{th} hospital's characteristics at time *t*, which are the number of general beds, ownership types (public, private, or other)[28], and the size of the population of municipality where the hospital is

28 While the number of hospital beds per 1,000 population is larger in Japan than in other OECD countries (for example, 2.71 in Sweden, 2.75 in Canada, 2.95 in United Kingdom, 3.05 in United States, 6.37 in France, 8.27 in Germany, and 13.4 in Japan (OECD, 2014)). In Japan, only 3.8% of hospitals are large hospitals, so that most hospital beds are medium-sized or small hospitals. The data in this study also shows that private non-profit hospitals occupy 66% of the medical care market, which is the largest proportion among all hospital types.

located[29]. As results of the balancing test, the difference in the mean values of all $X_{t,i}$ between control and treatment groups are statistically insignificant at the base line of 2000 and 2006[30]. W is the weight derived from the kernel propensity scoring matching between treated and the matched control hospitals. In practice, for each outcome, $\hat{\delta}$ is estimated as a coefficient of an interactive term of year dummy ([before] as 0 and [after] as 1) with D_i. I performed separate regressions for 2000 and 2006, by hospital size.

4. Results

4.1 Distribution of PNR and LHS over time

Figures 6 and 7 show histograms for PNR and LHS by the size of the hospital and the timing of the major revisions of FFS, respectively. These histograms are obtained using kernel density estimates[31]. During the baseline period (1984-1987), the mean/median PNRs are about 3.5/2.3, 6.7/3.3, and 9.6/6.4 with standard deviations of 4.0, 10.7, and 10.1 for large, medium-sized, and small hospitals, respectively, which decline to 1.2/1.1, 1.6/1.3, and 2.4/1.9, with standard deviations of 0.7, 0.8, and 2.1 in the period 2006-2008. Similar to PNR, the mean/median LHS in 1984-1987 are about 31.6/ 30.3, 33.7/28.6, and 41.8/37.8 with standard deviations of 9.3, 16.1, and 21.5 for large, medium-sized, and small hospitals, respectively, which decline to 18.0/16.7, 25.9/ 21.1, and 38.3/ 33.5, with standard deviations of 6.7, 15.0, and 22.7 in the period 2006-2008. However, the standard deviation for large hospitals has been shrinking over time, while the standard deviations

[29] Municipalities are divided into 4 categories depending on the size of their population: a "metropolitan area (MA)" with a population greater than one million; "rural urban center (RUC)" with a population greater than 0.3 million and less than or equal to 1 million; a "local small city (LSC)" with a population greater than 0.1 million and less than or equal to 0.3 million; and an "underpopulated area (UPA)" with a population of less than or equal to 0.1million.

[30] The results of the balancing test can be provided by the author, if it is requested by readers.

[31] In producing the estimates in Figure 6, I have eliminated hospitals where the PNR is more than 10 (about 5% of the sample).

for medium-sized and small hospitals have not changed.

Regardless of the size of the hospital, the distributions of PNR and LHS have been shifting to the left over time. However, the decreases in PNR and LHS seem to be drastic for medium-sized and large hospitals after the period, 1992-1999. Almost half of the large hospitals had already met the requirements for a "7:1" hospital before 2006, and consequently, 78% of the large hospitals attain an additional reimbursement after 2006. Medium-sized hospitals have been steadily catching up with the large hospitals in 2000-2005 and about 43% of medium-sized hospitals obtain the high reimbursement after 2006. For small hospitals, the PNR and LHS had begun to fall slightly in 2000-2005, and 20% of these hospitals have satisfied the new criteria after 2006.

[Figures 6 and 7 around here]

The distributions of PNR and LHS over time imply that large and even some medium-sized hospitals could predict the direction of the price policy change in the near future and make a decision even before the actual revision of the FFS. If that is the case, hospital characteristics would affect how fast a hospital responds to a change in pricing policy. So, balancing these characteristics between the control and treatment groups using a DID estimator on the common support with a kernel propensity score matching would be significant to identify the pure effect of a change in FFS on PNR and LHS.

4.2 Kernel propensity score matching DID estimates

Tables 1 and 2 present the results of estimating equation (2), before and after 2000 and before and after 2006, respectively. DID estimates ($\hat{\delta}$) show that the revision of the FFS

system in 2000 significantly decreases PNR by -0.19 and -0.04 (-0.13, in average) (p-value <0.01). However, the effect on PNR is not statistically significant for small hospitals. On the other hand, the revision in 2000 has the largest statistically significant effects on LHS in small hospitals of about -7.1 days, following -4.5 days and -2.9 days in large and medium-sized hospitals, respectively (-5.5 days, in average). Table 2 shows that the revision in 2006 does have statistically significant impacts, such that it would influence the PNR of each large and medium-sized hospitals, by -0.08 (p-value <0.1) and -0.07 (p-value<0.05). As with the effect of the 2000 revision, the PNR of small hospitals is less likely to be influenced by the 2006 revision. In contrast to PNR, regardless of hospital size, LHS is more likely to be affected by the 2006 revision, -6.9 days, -3.7 days, and -1.9 days for small, large, and medium-sized hospitals, respectively (-5.1 days, in average) (p-value <0.01).

[Tables 1 and 2 around here]

Looking at the DID estimates that pick up the impact of the revisions of the FFS in 2000 and 2006, the impacts on PNR for both medium-sized and large hospitals turn out to be statistically significant before and after 2000, rather than around 2006. After the revision in 2006 which introduced an additional reimbursement for "7:1" hospitals, there is a debate that medium-sized and large hospitals succeeded in increasing the number of their nursing staff, but this is not the case for small hospitals, about 80% of which are run by private organizations. Due to the limited number of nurses in the labor market, small hospitals, particularly in rural areas, which could not provide better salary and/or working conditions are at a disadvantage and completely failed to employ new additional nursing

staff (Moriyama, 2009). In contrast to that debate, the results here show that the decline in PNR after 2006 does not appear to be statistically significant as much as the one after 2000, probably because the declining trend of the PNR had already begun at an earlier time period just after 2000 when the PNR became significant factors for the revision of the FFS.

Interestingly, in contrast to the trends for PNR, both the 2000 and 2006 revisions seem to decrease LHS significantly, in particular, among small hospitals, where we could not observe statistically significant declines in PNR during the study periods. Although we observe improvements in the average LHS in small hospitals to some extent after the revisions, looking at the mean LHS in the treatment groups for small hospitals, LHS still remains longer than 40 days in the base line periods for both 2000 and 2006.

A decline in PNR could contribute to reducing the average LHS to less than 30 days in each medium-sized and large hospitals, approximately more than 50% and 70% of which are run by public or social insurance interested organizations (SIIO). This might be because public or SIIO hospitals are subsidized by the government more than private hospitals, to provide attractive working conditions including wages to nurses. But, if that is the case, it may not be sustainable. Consequently, the insolvent financial status of public hospitals could be a further fiscal burden for municipalities, particularly in rural areas. Therefore, as Iizuka and Watanabe (2014) pointed out with respect to physicians labor, local government hospitals may have to exit from the market due to the financial burden of hiring many nurses to maintain a relatively high PNR with a shorter LHS.

5. Conclusion

Overall, the empirical results in this study indicate that the revisions of the FFS system

in 2000 and 2006 have certainly achieved the policy objectives relating to the working conditions for nurses in medium-sized and large hospitals, but that is not the case in small hospitals. Further, regardless of hospital size, the "7:1" regulation is successful in shortening the average LHS, however it still remains longer than one month particularly in "non-7:1" small hospitals in the baseline periods.

In order to bring the average LHS for acute high-tech care with a PNR of "7:1" close to the mean of OECD countries (7.4 days in 2014) , intermediate facilities and clinics are necessary, where sub-acute, long-term, and home health care are provided. For example, a patient could promptly be treated at an expensive acute high-tech care hospital and, after a short stay at a high-tech hospital, he or she could be transferred to an intermediate care hospital or clinics for rehabilitation to go back to daily life at home. Considering the current increase in the number of old people living alone in the community without informal care givers, the demand for this type of care after acute medical treatments will be rising rapidly. For that purpose, health care resources such as physicians, nurses, and beds should be reallocated to sub-acute, long-term, and home health care, and therefore, the MHLW attempted to reduce the number of hospital beds for acute high-tech care to about 180,000 by 2025 when the baby boomers become 75 and older. A series of revisions of the FSS aim to clarify and differentiate the roles and functions of medical facilities with various characteristics, rather than motivate them all in the same direction to satisfy the high criterion for intensive care along with an additional reimbursement. Unfortunately, hospitals were not discouraged from adopting unsympathetic new standards for high reimbursement. As described in Figures 4 and 5, the number of general beds for acute care which met the requirements for a "7:1" hospital with high

reimbursement has increased up to 328,518 in 2010 (MHLW, 2012)[32]. This might be caused by the response of medium-sized and large hospitals a change in price policy in order to pursue higher reimbursement. However, this is not exactly what the MHLW intended. Consequently, the latest revision of the FFS in 2014 turned to decrease drastically the fee for inpatient hospital care provided by "7:1" hospitals, in order to motivate some hospitals to transfer from "7:1" acute care hospitals to "non-7:1" providing other type of care.

A lesson from this example is that constant quantitative evaluation of the impact of a price policy on the supplier's behavior is necessary, in particular, when a free hand choice is allowed for health care providers, to some extent, under a price regulation policy.

Finally, there are a number of limitations of this study. First, the econometric strategy in this study could not identify the effects of FFS revisions completely, since kernel propensity matching score DID could account for observable time-invariant effects, but unobservable influences still might remain within the model. Second, it did not evaluate the impacts of the FFS on patient outcomes and medical costs, where it could be quite challenging to identify pure effects because of the endogeneity problem between policy changes and outcomes. Finally, due to data limitations, the long-run effects of the critical revisions in 2006 have not been examined in this study. So, further research is necessary to clarify the effects of policy-changes on health care in Japan.

[32] Also, MHLW (2012) indicates that there are 248,606 beds in 10:1 hospitals, 33,668 beds in 13:1 hospitals, and 66,822 in 15:1 hospitals in 2010.

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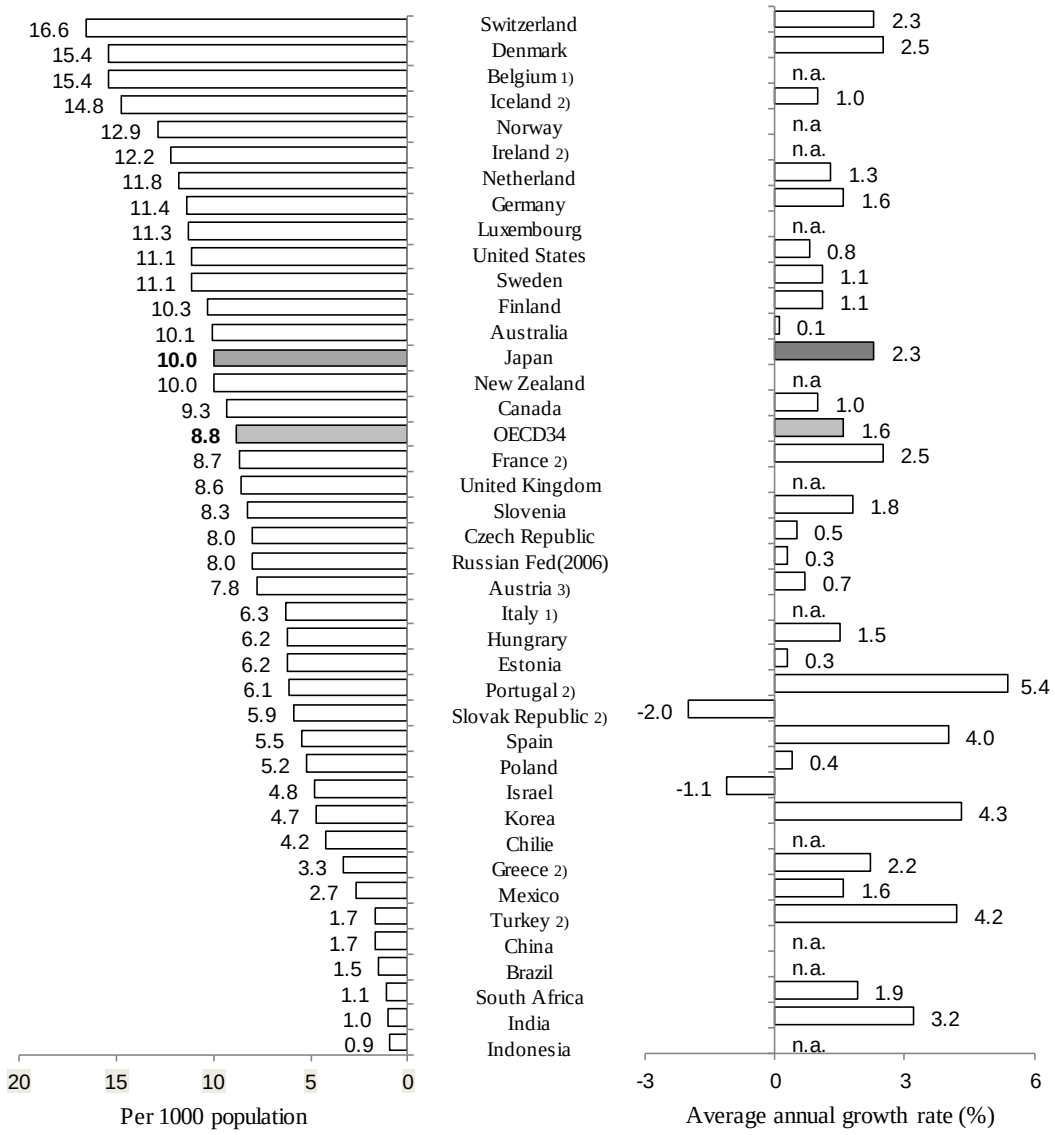
Fig.1 Practising nurses per 1,000 population, 2010 and change between 2000 and 2010



Notes

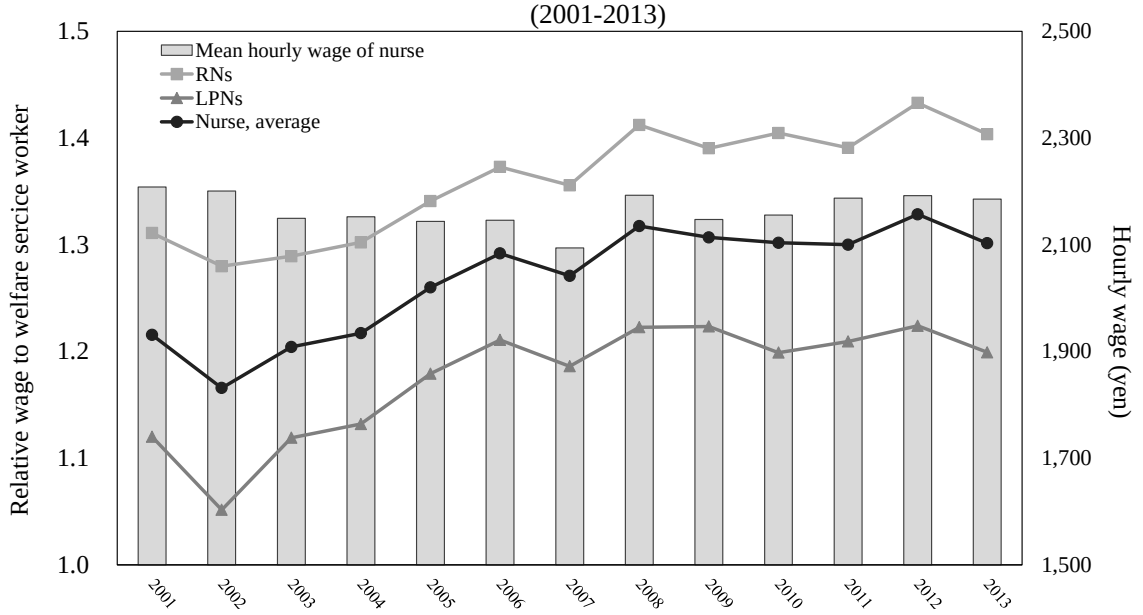
1) Data refer to all nurses who are licensed to practice.

2) Data include not only nurses providing direct care to patients, but also those working in the health sector as managers, educators, researchers, etc.

3) Austria reports only nurses employed in hospitals.

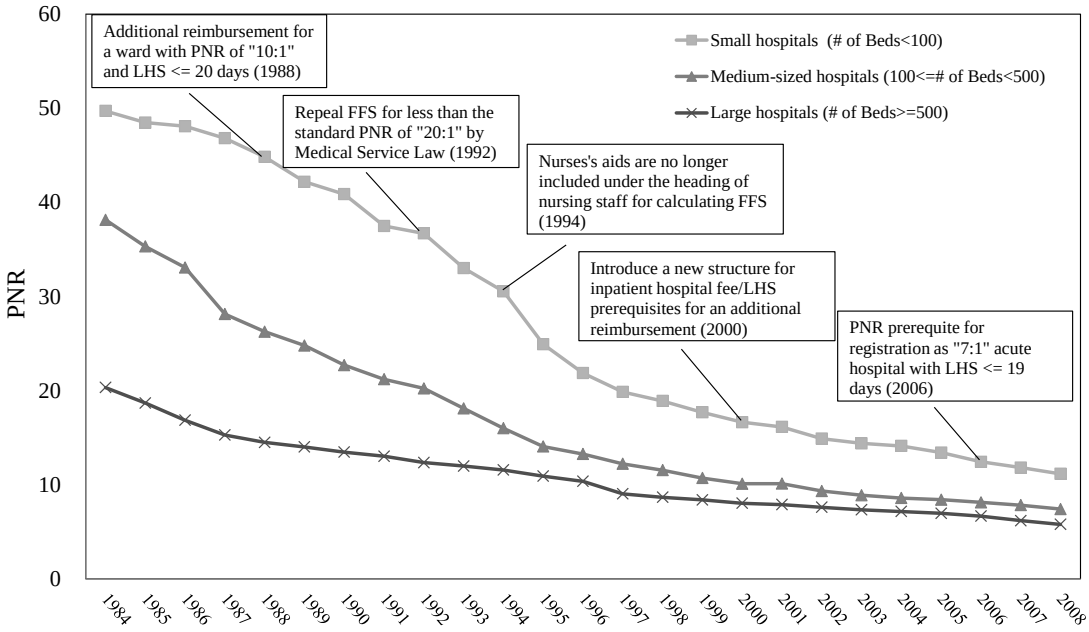
Source: OECD Health Data 2014; Eurostat Statistics Database; WHO European Health For All Database.

Fig2. Mean hourly wages of nurses and relative wage to welfare service worker (2001-2013)



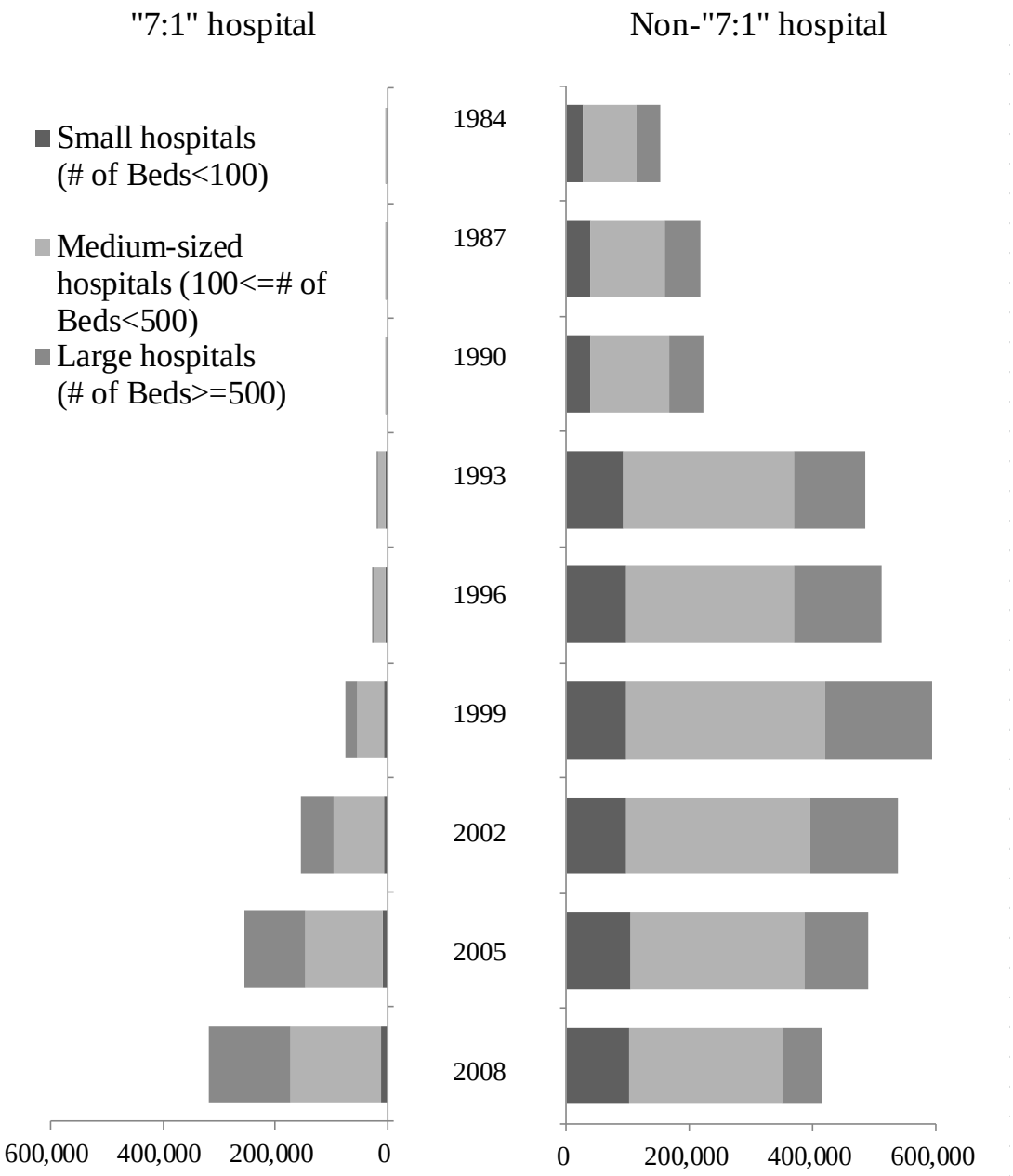
Source: MHLW. " Basic Survey of Wage structure: *Chingin kozo kihon toukei chousa: in Japanese*)"
Note: Mean hourly wage is calculated by annual income (including bonus)/total annual hours of working (including overtime work).
Welfare service worker includes physical/occupational therapists, care managers, care workers, and home helpers.

Fig.3 PNR by hospital size and the timing of major revisions of FFS (1984-2008)



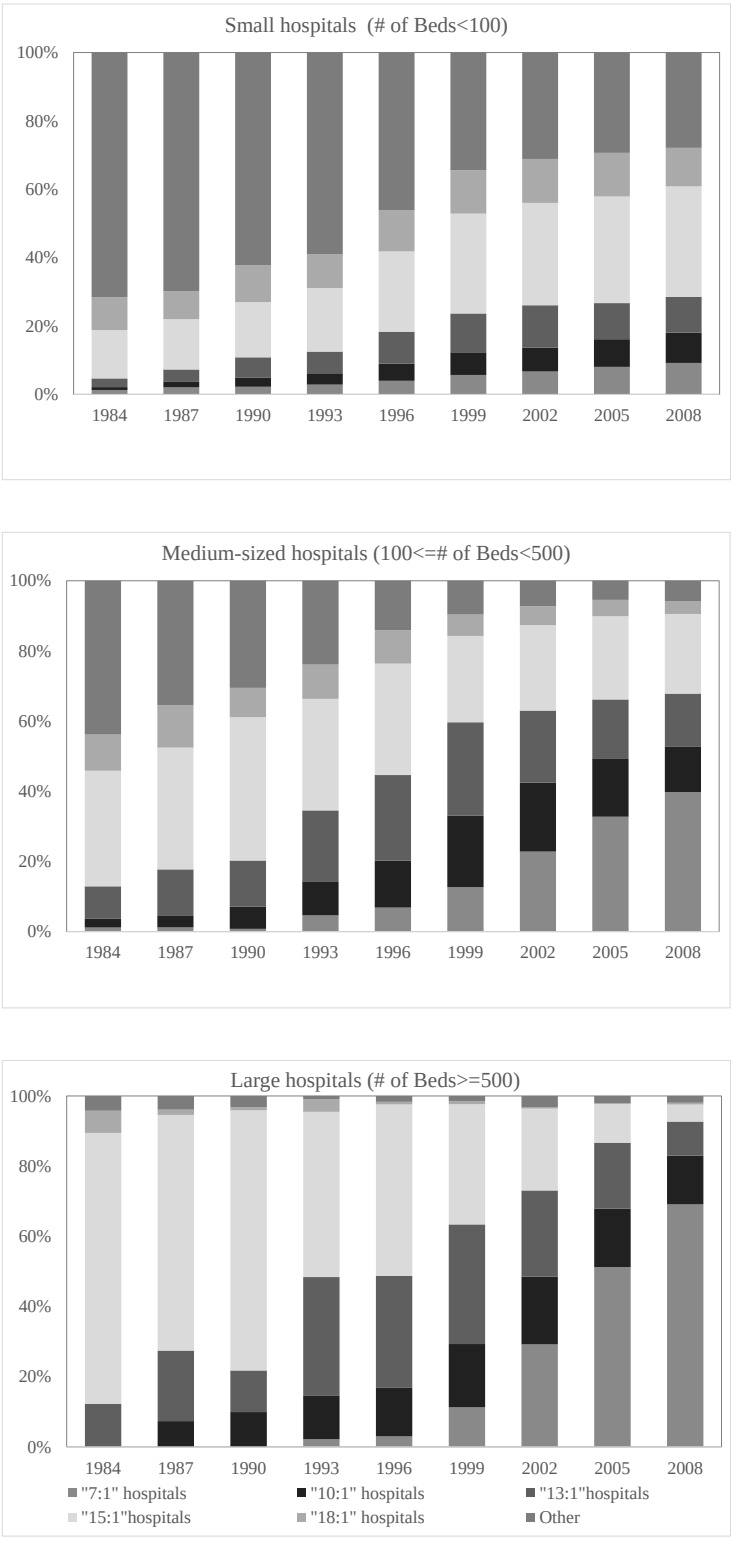
Source: PNRs are calculated by the author, based on "Hospital Report (HR)" and "Survey of Medical Institutions (SMI)" (MHLW).
Note: PRN and LHS stand for "patient-nurse ratio" and "length of hospital stay", respectively. All PRNs in this figure are based on the new standard revised as of 2006. Before 2006, each PNR of "7:1", "10:1", "13:1", "15:1", "18:1", and "20:1" were counted as "1.4:1", "2:1", "2.5:1", "3:1", "3.5:1", and "4:1" .

Fig.4 Number of general beds in hospitals
with PNRs of "7:1" versus more than "7:1", by hospital size



Source: Number of general beds, PNRs, and an average LHS are calculated by the author, based on HR and SMI (MHLW).
Note: "7:1" hospital is defined as a medical facility which satisfies PNR of 7:1 conditional on an average LHS of 19 days, while non-"7:1" hospitals do not meet the criteria.

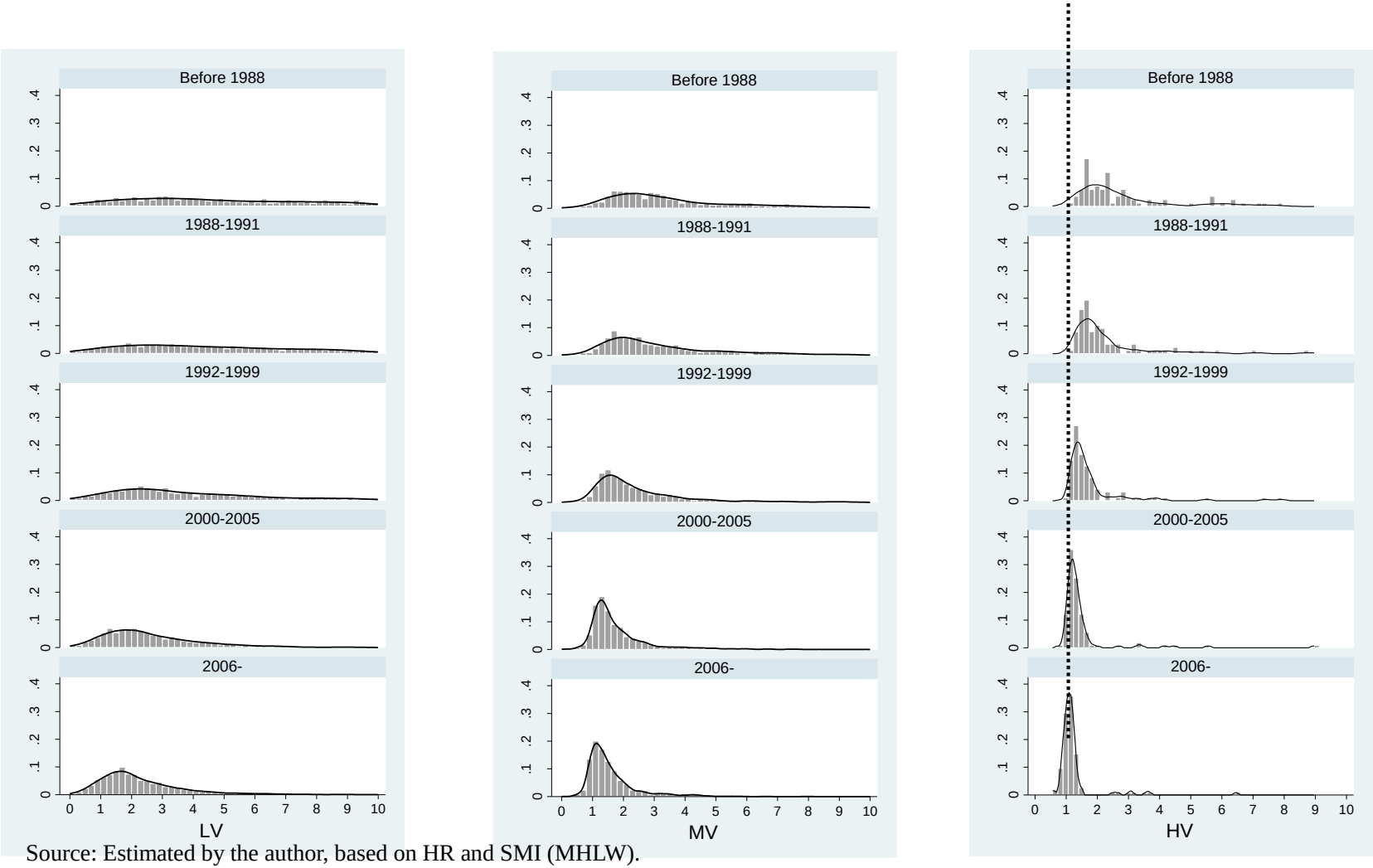
Fig.5 Distribution ratio of number of general beds, by hospital size and types of PNRs based on 2000 and 2006 criteria for additional reimbursements



Source: Distribution ratios are calculated by the author, based on HR and SMI (MHLW).

Note: The definitions of “10:1”, “13:1”, “15:1”, and “18:1” hospitals are based on the FFS revision in 2000 and "7:1" hospital was defined in 2006.

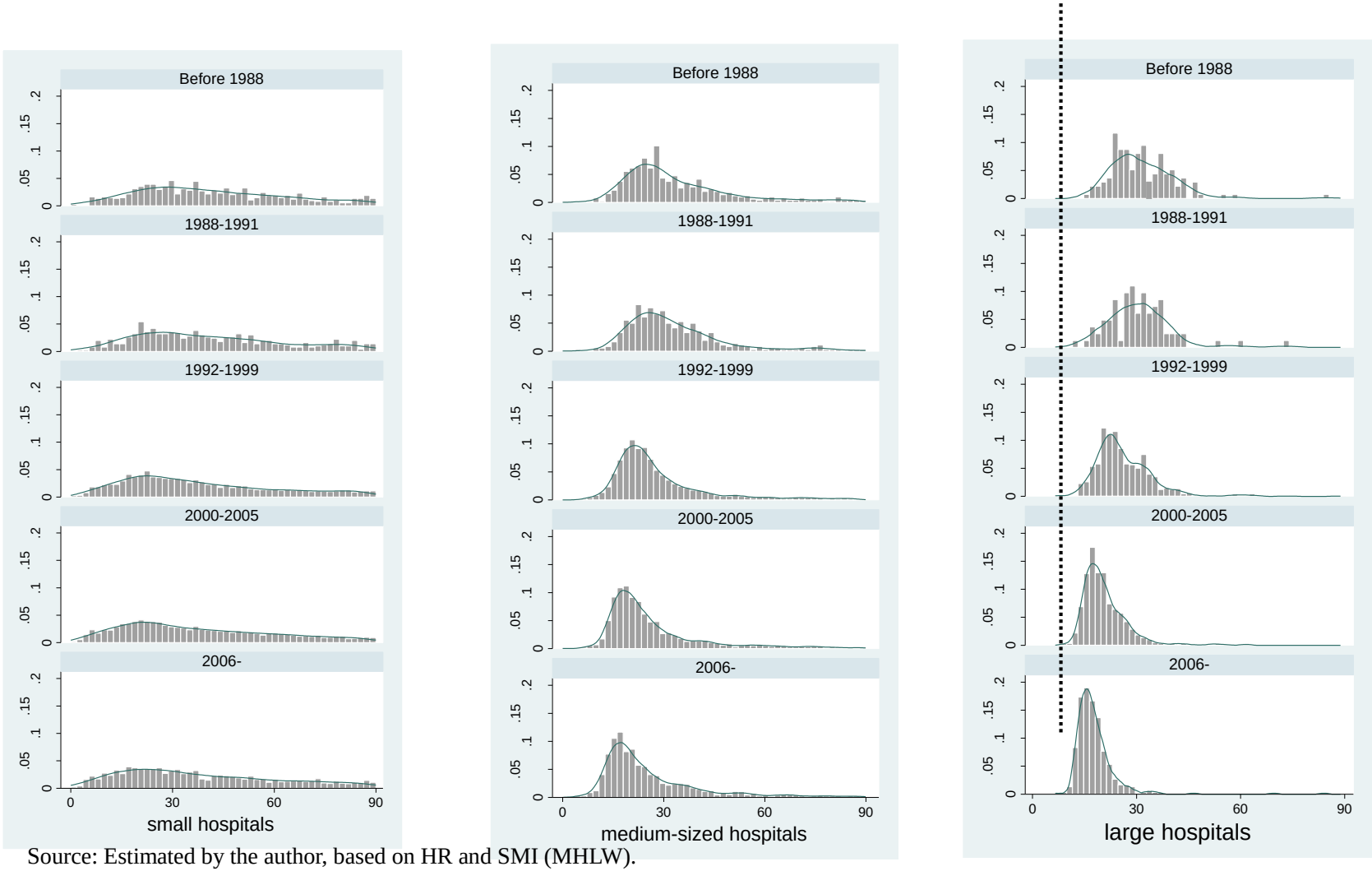
Fig. 6 Histogram of PNR by hospital size and the timing of major revisions of FFS with kernel density estimates



ospitals

Source: Estimated by the author, based on HR and SMI (MHLW).
Note: Broken lines show “a 7:1 hospital”.

Fig. 7 Histogram of LHS by hospital size and the timing of major revisions of FFS with kernel density estimates



spitals

Source: Estimated by the author, based on HR and SMI (MHLW).

Table 1 Kernel propensity score matching DID estimates before and after 2000

Outcome variables	Number of observations	Base line before 2000				Follow up after 2000				DID		R-square
		Control	Treated	Difference at base line		Control	Treated	Difference at follow up		δ in Eq.(2)		
A. PNR												
A-1. All hospitals	19501	1.042	1.644	0.602	***	0.880	1.352	0.473	***	-0.130	***	0.133
		(0.010)	(0.010)	(0.014)		(0.012)	(0.011)	(0.016)		(0.022)		
A-2. Small hospitals	9708	0.728	1.421	0.693		0.653	1.314	0.660		-0.032		0.127
		(0.016)	(0.016)	(0.022)		(0.022)	(0.020)	(0.030)		(0.038)		
A-3. Medium-sized hospitals	8214	1.357	1.968	0.612	***	1.008	1.429	0.421	***	-0.191	***	0.321
		(0.011)	(0.011)	(0.015)		(0.011)	(0.011)	(0.016)		(0.022)		
A-4. Large hospitals	1403	1.396	1.568	0.172	***	1.024	1.157	0.133	***	-0.040	***	0.338
		(0.016)	(0.016)	(0.022)		(0.016)	(0.016)	(0.023)		(0.032)		
B. LHS												
B-1. All hospitals	19501	20.549	36.849	16.300	***	20.917	31.758	10.841	***	-5.459	***	0.157
		(0.223)	(0.223)	(0.316)		(0.265)	(0.247)	(0.363)		(0.481)		
B-2. Small hospitals	9708	20.710	42.121	21.411	***	24.280	38.602	14.322	***	-7.089	***	0.189
		(0.359)	(0.359)	(0.508)		(0.493)	(0.432)	(0.655)		(0.829)		
B-3. Medium-sized hospitals	8214	19.790	31.080	11.290	***	18.495	26.924	8.429	***	-2.861	***	0.162
		(0.254)	(0.254)	(0.360)		(0.271)	(0.262)	(0.376)		(0.521)		
B-4. Large hospitals	1403	20.461	28.395	7.934	***	17.057	20.456	3.399	***	-4.536	***	0.259
		(0.374)	(0.374)	(0.529)		(0.383)	(0.384)	(0.542)		(0.758)		

Source: Estimated by the author, based on HR and SMI (MHLW).
Note: *** p<0.01; **p<0.05; and *p<0.1.

Table 2 Kernel propensity score matching DID estimates before and after 2006

Outcome variables	Number of observations	Base line before 2006				Follow up after 2006				DID		R-square
		Control	Treated	Difference at base line		Control	Treated	Difference at follow up		δ in Eq.(2)		
A. PNR												
A-1. All hospitals	21964	1.068	1.604	0.536	***	0.871	1.347	0.476	***	-0.060	*	0.100
		(0.009)	(0.009)	(0.012)		(0.021)	(0.020)	(0.029)		(0.031)		
A-2. Small hospitals	11272	0.850	1.442	0.591	***	0.734	1.327	0.594	***	0.002		0.093
		(0.013)	(0.013)	(0.019)		(0.036)	(0.032)	(0.038)		(0.052)		
A-3. Medium-sized hospitals	8859	1.433	1.887	0.454	***	1.014	1.401	0.387	***	-0.066	**	0.199
		(0.009)	(0.009)	(0.013)		(0.021)	(0.020)	(0.029)		(0.032)		
A-4. Large hospitals	1768	1.333	1.494	0.161	***	0.967	1.044	0.077	*	-0.084	*	0.196
		(0.013)	(0.013)	(0.018)		(0.028)	(0.029)	(0.040)		(0.044)		
B. LHS												
B-1. All hospitals	21964	21.514	38.033	16.519	***	22.542	33.958	11.416	***	-5.103	***	0.171
		(0.181)	(0.181)	(0.256)		(0.449)	(0.416)	(0.612)		(0.663)		
B-2. Small hospitals	11272	22.129	42.163	20.035	***	25.753	38.861	13.108	***	-6.927	***	0.193
		(0.282)	(0.282)	(0.398)		(0.772)	(0.680)	(1.029)		(1.103)		
B-3. Medium-sized hospitals	8859	20.532	32.342	11.810	***	18.766	28.706	9.940	***	-1.871	***	0.175
		(0.209)	(0.209)	(0.295)		(0.464)	(0.459)	(0.653)		(0.717)		
B-4. Large hospitals	1768	21.676	29.193	7.518	***	16.406	20.255	3.849	***	-3.669	***	0.241
		(0.289)	(0.289)	(0.409)		(0.637)	(0.654)	(0.913)		(1.000)		

Source: Estimated by the author, based on HR and SMI (MHLW).
Note: *** p<0.01; **p<0.05; and *p<0.1.

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Burden of Disease in Japan: Using National and Subnational Data to Inform Local Health Policy

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The Global Burden of Disease (GBD) study has been instrumental in guiding global health policy development since the early 1990s. The GBD 2010 project provided rich information about the key causes of mortality, disability-adjusted life years, and their associated risk factors in Japan and provided a unique opportunity to incorporate these data into health planning. As part of the latest update of this project, GBD 2013, the Japanese GBD collaborators plan to update and refine the available burden of disease data by incorporating sub-national estimates of the burden of disease at the prefectural level. These estimates will provide health planners and policy makers at both the national and prefectural level with new, more refined tools to adapt local public health initiatives to meet the health needs of local populations. Moreover, they will enable the Japanese health system to better respond to the unique challenges in their rapidly aging population and as a complex combination of non-communicable disease risk factors begin to dominate the policy agenda. Regional collaborations will enable nations to learn from the experiences of other nations that may be at different stages of the epidemiological transition and have different exposure profiles and associated health effects. Such analyses and improvements in the data collection systems will further improve the health of the Japanese, maintain Japan's excellent record of health equity, and provide a better understanding of the direction of health policy in the region.

Key words: Burden of disease, Japan, Comparative risk factor analysis, Health policy, Non-communicable disease, Aging

INTRODUCTION

The Global Burden of Disease (GBD) is a an essential tool in the global battle to improve health [1]. This project provides a systematic approach to calculating comprehensive, consistent, and comparable measures of health loss due to diseases, injuries, and their associated risk factors [2]. The latest GBD study, known as GBD 2010, was conducted by the Institute for Health Metrics and Evaluation (IHME) in collaboration with six academic partners worldwide including the University of Tokyo and was published in December 2012 [3,4]. In this study, the GBD research team introduced new analytical methods and a wider range of data. They also called on experts around the world to inform estimation methods with local advice and insights. Through these new approaches, the project's scope has expanded to cover 291 diseases and injuries in 187 countries from 21 regions, with estimations of these trends since 1990 [5]. The GBD 2010 also expanded on previous comparative risk factor analyses to cover a total of 67 risk factors [6].

The current iteration of the GBD, with its heavy focus on comparable and consistent disease burden and risk factor analyses between regions, makes it a useful tool not only for comparative health system assessment but also for planning

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public health programs and preventive interventions [7] and identifying gaps in international data systems [8]. For example, the GBD 2010 was able to describe trends in morbidity and mortality associated with the epidemiological transition in China [9]. The GBD studies can also be used, to some extent, for comparative health system assessments that allow for consistent and rigorous comparisons of health outcomes between countries with diverse social and health systems. For example, comparisons between the UK and the European Union clearly elucidated areas that were underperforming in the UK health system compared to its European counterparts [10]. Individual countries have also used the results of these comparisons to inform policy debate on issues specific to their own health needs. For example, Khang used the GBD 2010 results and project's detailed metrics to publish a review of non-communicable diseases (NCD) and strategies for NCD management in Korea [11].

Since the release of the GBD 2010 results, the GBD project has been aiming to not only include country experts but also create more detailed burden estimates using data that are only accessible to local researchers as well as at a sub-national level, where possible [12]. Sub-national estimates of disease burden and comparative risk would enable researchers and policy makers to explore variation and inequality within countries to better inform domestic and international health policy planning. As part of this effort to create detailed national estimates, the Department of Global Health Policy at the University of Tokyo has commenced a three-year project to update the GBD 2012 results at the national and sub-national level for Japan. This article describes the burden of disease, achievements in administering health care, future challenges, possible methods for estimating sub-national disease burden using the Japanese national burden of disease project, and the potential value of sub-national estimates of disease burden for policy makers in Japan.

THE BURDEN OF DISEASE IN JAPAN

Japan's achievements in health care administration have become a model for achieving good health at low cost. Japanese female life expectancy at birth has ranked number one globally since the 1980s. Life expectancy increased by 5.5% over 20 years, from 81.9 years in 1990 to 86.4 years in 2010 for females and from 75.9 years in 1990 to 79.6 years in 2010 among males [13]. After rapid improvements in life expectancy due to post-war advances in child health and vaccinations, this recent 20-year improvement has primarily resulted from the effective control of risk factors for NCD mortality [13,14]. For example, reductions in stroke-related mortality have occurred against a backdrop of low inequality and universal health coverage [15].

Table 1 shows the highest-ranked causes of disability-adjusted life years (DALYs) in Japan in 1990 and 2010 based on the GBD 2010 results [16]. In 2010, the highest-ranked causes of DALYs in Japan were lower back pain, cerebrovascular disease, and ischemic heart disease. These causes of DALYs are associated with increasing age and have been the highest-ranked causes of DALYs since 1990. Of the 25 most important causes of DALYs, road injury showed the largest decrease, falling by 42% from 1990 to 2010; however, self-harm remains one of the most important causes of DALYs.

Table 1. Top ten causes contributing to disability-adjusted life years in Japan in 1990 and 2010

Rank	1990	2010
1	Cerebrovascular disease	Low back pain
2	Low back pain	Cerebrovascular disease
3	Ischemic heart disease	Ischemic heart disease
4	Stomach cancer	Lower respiratory infections
5	Lower respiratory infections	Other musculoskeletal
6	Road injury	Lung cancer
7	Self-harm	Self-harm
8	Other musculoskeletal	Stomach cancer
9	Neck pain	Neck pain
10	Lung cancer	Falls

From Institute for Health Metrics and Evaluation. Global Burden of Disease country profile: Japan. Seattle: Institute for Health Metrics and Evaluation; 2012 [16].

Table 2. Top ten risk factors contributing to disability-adjusted life years in Japan in 1990 and 2010

Rank	1990	2010
1	Dietary risks	Dietary risks
2	High blood pressure	High blood pressure
3	Smoking	Smoking
4	Alcohol use	Physical inactivity
5	High fasting plasma glucose	High body mass index
6	Ambient PM pollution	High fasting plasma glucose
7	High body mass index	Alcohol use
8	Occupational risks	Ambient PM pollution
9	High total cholesterol	High total cholesterol
10	Drug use	Occupational risks

From Institute for Health Metrics and Evaluation. Global Burden of Disease country profile: Japan. Seattle: Institute for Health Metrics and Evaluation; 2012 [16].
PM, particulate matter.

Table 2 shows the contribution of the 10 most important risk factors to DALYs in Japan, also drawn from the GBD 2010 project [16]. In 2012, a country-specific comparative risk assessment was conducted in Japan under the GBD framework. This assessment explored these risk factors in more detail using 2007 datasets and focused on mortality rather than DALYs. This national assessment used a systematic review of the literature and analysis of locally available exposure data to build a more detailed picture of these risk factors than was otherwise made available at the global level by the GBD 2010 project. In doing so, this national assessment focused on only the top 16 risk factors for ill health in Japan and developed a measure of joint risk to represent the complexity of dietary risk factors, which are difficult to analyze separately. This national assessment also used richer data to estimate contributions to lost life expectancy and probability of death among these risk factors. In turn, this analysis provided a slightly different insight compared to results based only on DALYs such as in the GBD 2010 results. These results provide more detail about the relative balance of risks; however, the more detailed data sources and restricted set of risk factors has led to some differences with the GBD 2010. Nevertheless, both the GBD 2010 and this 2012 national assessment revealed the same top three risk factors including dietary risks, high blood pressure, and smoking, and the 2012 national assessment estimated the effect of these risk factors on life expectancy and mortality. The 2012 national burden of disease analysis was in broad agreement with GBD 2010 and demonstrates the power of a national burden of disease estimation conducted under the GBD framework [17].

Figure 1 shows the contribution of the top 16 risk factors in Japan to changes in life expectancy at 40 as well as the change in probability of death in the 15 to 60 and 60 to 75 year age groups. Smoking remains a key risk factor among men in Japan and is responsible for a total of nearly 2 years of lost life expectancy at the age of 40 and almost a 15% increase in mortality for men aged between 15 and 60 years old. For women and men, a complex joint risk factor profile built from high blood pressure, blood glucose, low-density lipoprotein cholesterol, and body mass index is responsible for a large proportion of the mortality. In women, this joint risk factor profile alone accounts for nearly a 1.5-year change in their life expectancy at 40. Therefore, Japan's preventive health and public health goals in the immediate future should be focused on the management of hypertension and risk factors for stroke and coronary heart disease that are embedded in this joint risk factor model as well as continuing to emphasize dietary interventions and improved management of suicide risks and depression.

SUB-NATIONAL ESTIMATES OF RISK AND MORTALITY IN JAPAN

It has been suggested that inequality based on region, cause, and wealth [18] as well as other risk factors that influence mortality are increasing in Japan [19]; however, these trends have changed since the early 1990s due to economic stagnation and other social determinants of health [20]. Given the regional variations in health financing and performance [15] and the challenges facing Japan's health system in the future [21], a detailed understanding of the sub-national variations in the causes of death and illness as well as their associated risk factors is essential.

Initial research that focuses on identifying variations among the causes of death at prefectural and municipal level may be the most effective tool to inform sub-national health policy making. Figure 2 shows the crude mortality rate among 50 to 59 year olds in Japan in 2010 [22] and the different patterns of mortality across the country. A broad tendency towards higher mortality was found in the north. Variations in the culture of these areas, urban planning, and the different income structures and lifestyle patterns across Japan may explain these variations in risk.

The use of geographical differences in mortality demonstrates the role that sub-national burden estimates can play in identifying variations in health and indicate possible causes of future divergence in health outcomes between regions. By conducting a sub-national analysis, it is possible to identify region-specific health intervention needs and begin constructing a local policy framework from data collected at the national level.

THE ROLE OF SUB-NATIONAL ESTIMATION IN POLICY DEVELOPMENT

The 2011 *Lancet* series on Japan identified major policy challenges facing the Japanese health system, considering that its universal health care system serves one of the most rapidly aging populations. Moreover, this series recommended that prefectural governments play a key role in forming and

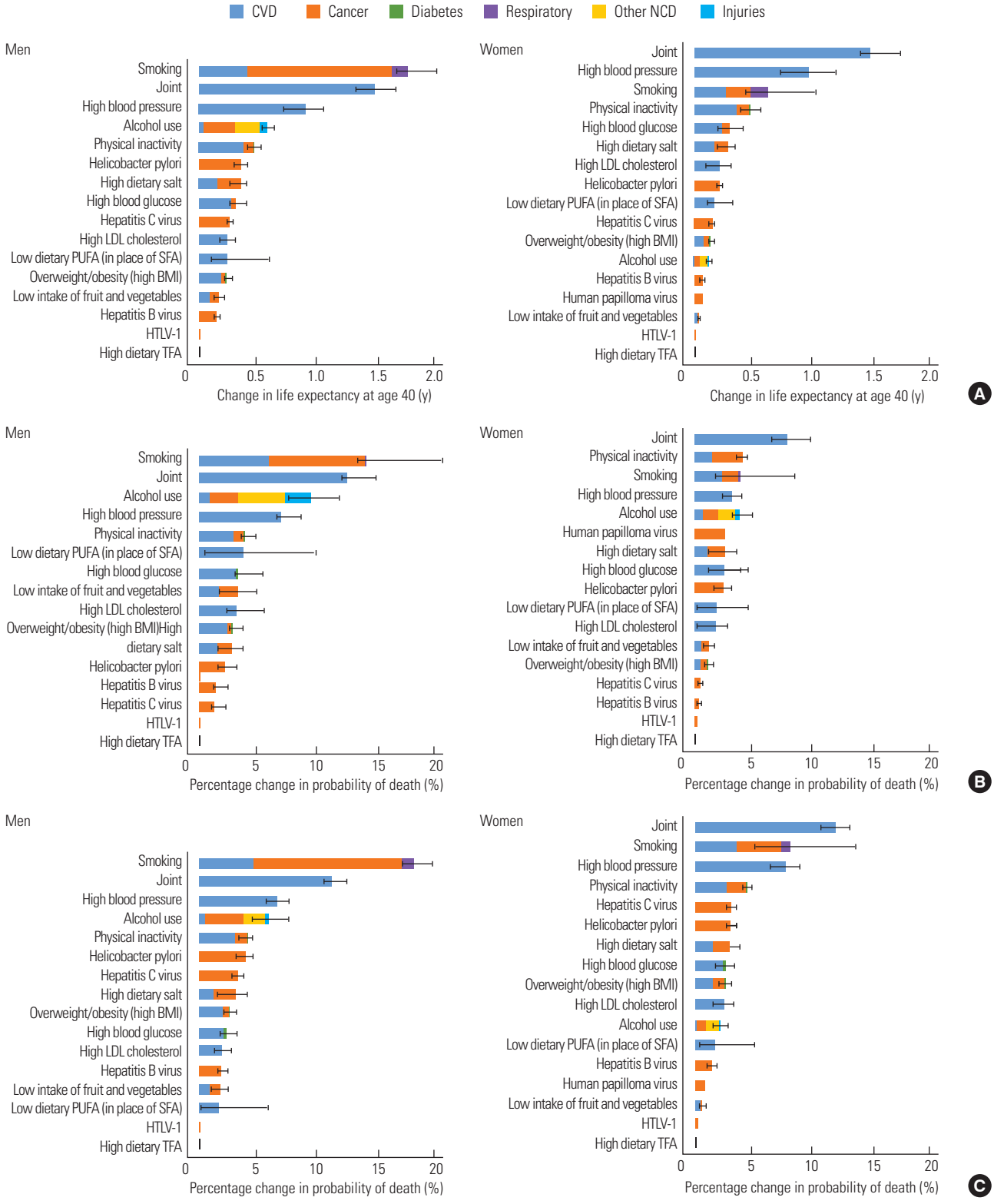

Figure 1. Influence of the 16 key risk factors on mortality outcomes in Japan in 2007. (A) Effect of risk factors on life expectancy at age 40. (B) Percentage change in probability of death at age 15 to 60. (C) Percentage change in probability of death at age 60 to 75 years. Ikeda N, et al. PLoS Med 2012;9(1):e1001160, according to the Creative Commons Attribution License [17]. LDL, low-density lipoprotein; PUFA, polyunsaturated fatty acids; SFA, saturated fatty acids; BMI, body mass index; HTLV-1, human T-lymphotropic virus-1; TFA, trans-fatty acids; CVD, cerebrovascular disease; NCD, non-communicable diseases.

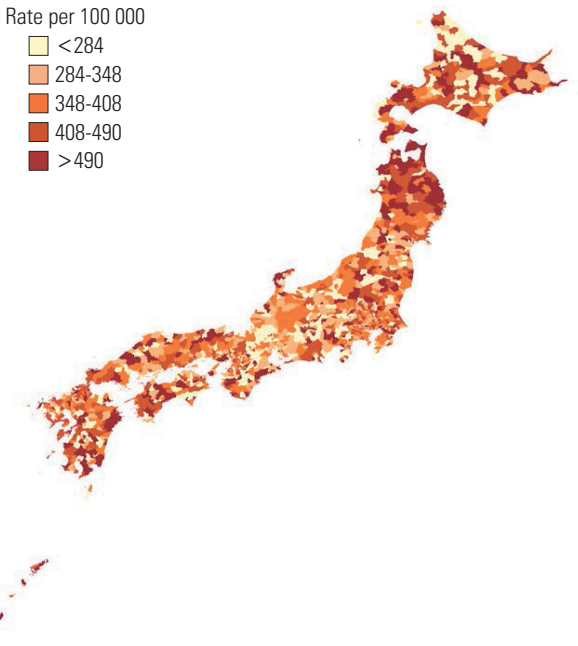

Figure 2. Mortality rate among 50 to 59 years old Japanese women in 2010. From Vital Health and Social Statistics Division. Vital statistics in Japan 2011. Tokyo: Ministry of Health Labour and Welfare; 2013 [22].

implementing health policy because of the huge regional variations in health insurance premiums within Japan [21]. However, for prefectural governments to play this role they will need to have access to high quality data on both the health challenges of their communities, the major risk factors for ill health, and past trends in these risk factors. Sub-national burden of disease estimates are an ideal tool for engaging with policy-makers, and the visualization tools developed by the IHME, such as the GBD compare tool [23], make it possible for policy-makers with little knowledge of epidemiology to quickly and easily compare their prefectural health profile with both their own historic profile and the profile of other prefectures.

In addition to enabling the development of locally driven plans to modify key risk factors and develop plans to reduce future health burdens, these local profiles also enable prefectural governments to identify gaps in the data and make investments in high quality data collection systems. For modern health planning, collecting high quality data is essential. Just as the GBD projects have revealed areas for improvement in data collection systems globally [8], so too will the local profiles naturally lead local organizations to improve their own local data systems. This kind of local response to gaps in the data may also lead to bottom-up pressure for the development of high quality data at a national level as prefectural government planners who assign priorities and plan for future health needs begin to understand the importance of burden estimates where national-level data systems are lacking.

However, national and sub-national burden of disease calculations cannot be the only analyses. One of the key methodological advances of the GBD study is the use of data across regions so that nations with sparse data in one health area can draw information from data available for other countries in the region. This process of data synthesis can also be used for national and sub-national estimates. Regional collaborations will enable nations at the same stage of epidemiological transition to share data on exposure risks and effect sizes, especially where exposures are more common in one nation or sub-national region than another. This kind of collaboration will also enable these nations to draw on the experience of others further along this epidemiological pathway, enabling better estimates of current and future NCD burden. Both technically and institutionally, collaboration is essential to improving GBD estimates and national and sub-national burden estimations.

DISCUSSION

In 1990 and 2010, Japan had the lowest age-standardized mortality rate and age-standardized rate of years of life losts globally [24]. Japanese life expectancy increased from the late 1950s and remained the highest in the world at the end of the 1980s. The early increase in longevity during the 1950s to 1960s has been credited to the implementation of effective infectious disease control programs [14], with the Japanese government enacting 32 health laws within ten years after the end of World War II [24]. Interventions that prevented infant and child mortality at that time included clean water, institutional delivery, and universal vaccinations. Subsequently, the implementation of preventive measures against NCD mortality and the maintenance of an equitable and accessible universal health system assured continued gains in the health of the Japanese population throughout the epidemiological transition [13]. Because of these interventions, Japan came to represent a model for universal health development [15,25], and these achievements are reflected in the results of the GBD 2010 project.

Although Japan performed well in promoting the popula-

tion's health status, several challenges for the Japanese health system remain. Cancer, heart disease, and cerebrovascular disease, the three leading causes of death, have contributed to approximately 50% of the population's lifetime risk [17]. Therefore, reducing NCD mortality is the key to prolonging the population's longevity. Lifestyle risk factors such as smoking are the most important factors associated with NCDs. Japan has successfully reduced the population's average blood pressure, which can be associated with an unhealthy diet, but the management of other lifestyle risk factors is still important. The next challenge for dietary interventions involves improving the methods used to address the complex joint risk factors including high blood pressure, blood glucose, low-density lipoprotein cholesterol, and body mass index. These complex risk factors are associated with urbanization, aging, and dietary changes as more Western food is incorporated into Japanese diets. Therefore, sophisticated interventions and policies at both the national and local level will be required.

Although smoking rates have been declining in Japan, smoking is still the leading preventable risk factor accounting for approximately 50% of adult mortality among young men [26]. Highly effective policies for tobacco control are needed in Japan, such as higher cigarette prices and stricter tobacco control ordinances consistent with the Framework Convention on Tobacco Control [27]. Another challenge for the Japanese health system is reducing mortality and morbidity rates associated with self-harm. More than 30 000 suicides have occurred in Japan every year since 1998, and, although the government has implemented several interventions and strategies to prevent suicide, no substantial improvements have been noted [28]. Therefore, effective interventions in the community and in workplaces are necessary for self-harm prevention.

Although Japan's health system is famous for maintaining equity in health coverage [25], we have shown that significant variations in patterns of mortality and risk are evident by age, region, and wealth. Maintaining equity in the future will require interventions and policy instruments to target these regional- and wealth-based inequities. Moreover, any policy development should rely on the analysis of risk factors using high quality data available at the regional and local level. Beginning with analyses at the prefectural level, it is our goal to develop estimates of years of life lost to death and disability as well as the major contributing risk factors within the GBD framework to guide policy development and inform local health decisions. These sub-national estimates will help to inform national and prefectural governments about evident health challenges and provide detailed assessments of disease burden to those who allocate resources and plan interventions. In addition, these sub-national estimates will provide renewed impetus to reform the relationships between central and local governments as well as improve data systems and research [21].

Results of the new GBD 2013 study, which will become the most recent burden of disease study, are scheduled to be published in late 2014 [4]. This new GBD study will estimate trends in the burden of disease throughout 1990 to 2013 with the addition of more risk factors than were included in the GBD 2010. This iteration of the GBD project also aims to use data that are directly available from national collaborators. Since the release of GBD 2010, the IHME has been actively seeking collaborators at the national level to provide more accurate, comprehensive, and detailed data as well as to give expert advice on the findings. A study as broad and complex as the GBD project requires many simplifications and approximations, but also has many gaps in the data and local knowledge. By incorporating national-level collaborators and detailed data, estimates that are even more accurate will hopefully be produced and updated frequently. We aim to incorporate our sub-national estimation process into the next round of the GBD project, thus enabling our results on sub-national variation and inequality to inform the data on national and sub-national variation in other parts of the region, which is similar to how the variations between nations has informed estimates within regions in the GBD 2010 project [5].

CONCLUSION

The GBD framework has been essential to understanding the successes and challenges in reducing mortality and the burden of health in Japan. By providing comprehensive information on the national and sub-national disease burden, the GBD studies will be crucial in informing future agendas and policies in countries throughout the region and especially in Japan. However, the quality of the GBD outcomes is dependent on the commitment and involvement of country-level collaborators. Nations throughout Asia should commit to this unique and challenging project and encourage epidemiologists throughout the region to participate.

ACKNOWLEDGMENTS

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CONFLICT OF INTEREST

The authors have no conflicts of interest with the material presented in this paper.

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Farewell to free access: Japan's universal health coverage

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While the Obama administration is struggling to achieve universal health coverage in the US, Japan celebrated the 50th anniversary of its universal health coverage system in 2011. Japan's universal health insurance coverage is now deeply rooted in both patients' and doctors' minds. But the principle of 'free access' to medical procedures and medications is being challenged by the economic realities of sustaining this system.

Under Japan's current health insurance system, a uniform fee schedule, which the government determines, regulates the price of all medical procedures and drugs. In sharp contrast to American doctors, who believe in their 'professional freedom' of deciding the prices they charge, Japanese doctors rarely question government regulations in the sector. The price of health care is uniform throughout the country and people can receive care at any clinic or hospital so long as they contribute to the specified co-payments, which is often around 10–30 per cent. 'Free access' is the core principle of Japan's universal health coverage maintained in the last half century, in which patients have full freedom to choose their own health care providers and all approved drugs are covered by insurance. Japan's universal health coverage negates the need for things such as managed care, gatekeepers, preauthorisation and restrictive formularies. And in the absence of control on the supply side, Japan has become a country most heavily equipped with medical facilities and technology among OECD member countries in terms of the number of hospital beds, dialysis units, CTs and MRIs per population.

But free access to new and expensive drugs is increasingly placing a strain [1] on Japan's health insurance system. When Japan achieved universal health coverage over 50 years ago,

medical care and drugs were primitive and cheap. Free access was economically feasible. But development and innovation of medical technology brought about effective but expensive drugs — the most expensive being Zevalin, which is used to treat lymphoma. One set of Zevalin comes with a price tag of US$26,000 (AU$29,000). One set of Ilaris, used to treat rare paediatric chronic diseases, comes with a price tag of US$14,000 (AU$15,600). And unlike Zevalin, which is for one-off use, patients may need multiple repeats of Ilaris. Under Japan's current universal health coverage, doctors are free to prescribe expensive drugs such as Zevalin and Ilaris without any pre-authorisation. Patients, of course, will have to contribute to co-payments of approximately 10–30 per cent, but can claim back the amount exceeding certain limits from their insurers.

In 2013, the Central Social Insurance Health Care Committee (CSIHCC), which reviews the revision of the uniform fee schedule as well as the drug price list every two years, proposed to introduce economic evaluation in granting the health insurance coverage and setting prices. Economic evaluations will aim to measure how much it will cost to prolong one year of life for anti-cancer drugs, and how much it will cost to improve the quality of life for drugs for chronic diseases in comparison with other existing, less-expensive drugs or treatments. Drugs must be effective to be approved — but must be effective enough to justify their price tags to be covered by Japan's insurance system. CSIHCC will first establish methodology and standards to carry on economic evaluation and plans to introduce it in as early as 2016. Thresholds of £20,000–30,000 (AU$37,000–55,000) for prolonging one quality-adjusted year of life used in the UK National Health Service were quoted in the discussion paper presented at CSIHCC.

At present, all approved drugs are automatically covered by insurance and prices were set to ensure pharmaceutical manufacturers to recoup the investment for new drugs. It is not yet certain what threshold will be adopted nor if any drugs in the present price list will be excluded from insurance coverage. One thing is certain: it is a radical departure from the 'free access' principle that came with Japan's universal health coverage over half a century ago. If a patient wants access to medication that is not covered by insurance, he or she will be required to pay fully out of pocket. Inevitably, patients will be selected based on their ability to pay. Also, in economic evaluation, lives are not treated equal. One year of life in pain and agony is valued less than one year of life in full health. The aforementioned thresholds may be lowered if the drug is not effective enough to achieve full health.

The departure from the 'free access' principle currently in place in Japan is an inevitable compromise to sustain universal health coverage into the future. For now, Japan will have to face a grim fact that lives are not created equal.

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ORIGINAL ARTICLE

The global economic crisis, household income and pre-adolescent overweight and underweight: a nationwide birth cohort study in Japan

P Ueda[1,2], N Kondo[3] and T Fujiwara[4]

BACKGROUND: We hypothesized that children from lower income households and in households experiencing a negative income change in connection to the global economic crisis in 2008 would be at increased risk of adverse weight status during the subsequent years of economic downturn.

METHODS: Data were obtained from a nationwide longitudinal survey comprising all children born during 2 weeks of 2001. For 16,403 boys and 15,206 girls, information about anthropometric measurements and household characteristics was collected from 2001 to 2011 on multiple occasions. Interactions between the crisis onset (September 2008) and household income group, as well as the crisis onset and a >30% negative income change in connection to the crisis, were assessed with respect to risk of childhood over- and underweight.

RESULTS: Adjusted for household and parental characteristics, boys and girls in the lower household income quartiles had a larger increase in risk of overweight after the crisis onset relative to their peers in the highest income group. (Odds ratio (95% confidence interval) for interaction term in boys = 1.23 (1.02–1.24); girls = 1.35 (1.23–1.49) comparing the lowest with the highest income group.) Among girls, an interaction between the crisis onset and a >30% negative change in household income with respect to risk of overweight was observed (odds ratio for interaction term = 1.23 (1.09–1.38)). Girls from the highest income group had an increased risk of underweight after the crisis onset compared with girls from the lowest income group.

CONCLUSIONS: Boys and girls from lower household income groups and girls from households experiencing a negative income change in connection to the global economic crisis in 2008, may be at increased risk of overweight. Vulnerability to economic uncertainty could increase risk of overweight in preadolescence.

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INTRODUCTION

Childhood overweight is a serious public health challenge globally.[1] Although Japan has lower rates compared with many other high-income countries, the problem is increasing. In 2007, ~10% of the 6–11-year old children were overweight; a prevalence twice as large as that recorded in 1978.[2]

Socioeconomic disadvantage has in numerous studies been linked to childhood overweight, although the association differs depending on study setting, sex and ethnicity.[3–5] Exposure to negative life events and psychosocial stressors in childhood—including parental stress and financial problems—may also increase risk of childhood overweight and obesity.[6–9]

During the past 20 years of economic recession in Japan, growing socioeconomic disparities have been observed.[10] Concern for further erosion of social security arose in the fall of 2008 as Japan was one of the countries hardest hit by the global economic crisis. Gross domestic product dropped by 6.3% in 2009 and unemployment rates increased from around 4% in the first half of 2008 to 5.5% in July 2009.[11] The crisis disproportionally affected the low-income groups and workers with precarious employment; income inequality and poverty rates rose considerably,[12] and social welfare programs have been unable to provide adequate support to those in need.[13]

In other high-income countries, the economic downturn has been linked to deteriorated health and increased psychosocial problems among children, in particular those from lower socioeconomic groups.[14]

Against this background, it is of relevance to assess the potential effects of the recent economic downturn on weight status among children in Japan. We examined the relation between household income and trajectories in weight statuses throughout the period of the economic crisis, using data from a nationwide longitudinal birth cohort study. Children in this cohort were born in 2001, and were thus exposed to the economic downturn at a possibly sensitive age for the development of overweight.[2,15] In addition, we evaluated trajectories of underweight prevalence as underweight may be associated with socioeconomic factors[16,17] and constitutes a health issue among girls in Japan[14] and other Asian countries.[18]

MATERIALS AND METHODS

This study was based on data from the Longitudinal Survey of Newborns in the 21st Century, conducted by the Ministry of Health, Labour and Welfare in Japan between the years 2001 and 2011. All babies born in Japan between January 10 and 17, and July 10 and 17 in 2001 were identified using the birth record list of vital statistics for Japan ($n = 53,575$).

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Questionnaires were sent to parents with mail when the children were 0.5, 1.5, 2.5, 3.5, 4.5, 5.5, 7, 8, 9 and 10 years old. Parents returning the questionnaires to the Ministry of Health, Labour and Welfare were regarded as approving participation in the study. In total, 47,015 questionnaires were returned at 6 months, corresponding to an 88% response rate. A total of 10,753 children were excluded as parents did not report weight and height on at least one occasion before the crisis onset and after the crisis onset, respectively, and 4,653 children were then excluded as income for at least 1 year before and after the crisis onset were not recorded. This gave us a sample of 31,609 children (67% of the responding subjects), of which 16,403 were boys and 15,206 were girls. The study was exempt from approval by the Institutional Review Board as it was conducted by the Ministry of Health, Labour and Welfare and the data were stripped of all information enabling identification of individuals.

Parents were asked to report weight (to the nearest 0.1 kg) and height (to the nearest 0.1 cm) of the child as well as date of measurement. Body mass index (BMI) was determined according to the formula: weight (kg)/height^2 (m). Overweight and underweight were defined using age (by month) and sex-specific cut points from the International Obesity Task force starting from 2 years of age. The cut points correspond to a BMI of >25 (overweight) and <18.5 (underweight) at 18 years of age.

Other variables

Parents reported household income (father's income, mother's income and other incomes) for the years 2001, 2002, 2004, 2005, 2006, 2007 and 2010. The average household income for the years before the downturn in 2008 was compared with the household income in 2010 (after the crisis onset). Variables were generated for income reductions of >30, >20 and >10%.

Number of household members was recorded in questionnaires from the years 2002, 2005 and 2006. Household income was divided by the square root of the number of household members[19] for these years and income quartiles before the onset of the economic crisis were determined based on the average of the obtained values.

Father's and mother's education were reported at the 1.5 years follow-up and categorized into junior high school, high school, vocational school and higher education. Parents' age at birth of the child was categorized into <20, 20–24, 25–29 and >29 years. Residential area in 2011 (last follow-up) was grouped into the 20 designated cities as specified by the Japanese government, other cities and rural areas. Children were categorized as belonging to a three generation household—a potential risk factor for childhood overweight in Japan[20]—if at least one grandparent was living in the household in 2011.

Statistical analysis

Data were analyzed in STATA SE statistical package, version 12.1. As previous studies have found differences between the sexes in associations between socioeconomic and psychosocial factors and risk of overweight[9,21] as well as risk patterns for underweight,[22,23] we performed separate analyses for boys and girls.

In our primary analyses, we assessed the changes in weight status in children before and after the onset of the economic downturn with respect to income quartile, and a >30% income reduction in connection to the crisis. We calculated odds ratios (ORs) for overweight and underweight, respectively, using a generalized estimating equation model,[24] with an exchangeable correlation structure. Data were based on 1-month intervals starting from January 2003 when the first batch of children included in the survey reached 2 years of age. To explore the potential point of changes in trajectories of the risks for developing over-/underweights, we carried out a series of analysis. The first model (model 1) included an age variable and a term for the crisis onset to assess the potential change in risk of the outcomes across the whole population during the study period and after the onset of economic downturn. Interaction terms for the step term (a dummy variable representing a potential time point of weight trajectory changes) and income quartile, and the step term and income reduction were also included to assess if changes in risk differed between the income groups and between the groups experiencing >30% income reduction and those that did not. To assess model fit for different step terms, Bayesian information criterion was compared between models with alternative step terms by 3-month intervals from June 2008 to December 2009. Our preliminary analysis showed that Bayesian information criterion was lowest for the model with the step term for September 2008 (data not shown) Thus, September 2008 was used for the step term in all analyses. In the next step (model 2), analyses were further adjusted for potential confounding factors including parents' education and age, household composition (two parent household, single parent household, three generation household) and residential area.

Dummy variables were created for missing data on covariates and included in the analyses. We also performed analyses on income reductions between other years (2001–2004 vs 2005 and 2001–2005 vs 2007); using alternative income reduction cut offs, namely, of >20 and >10%; and excluding subjects with missing data on covariates.

RESULTS

The average annual household income of the years before the crisis onset by income quartiles were (in Japanese yen (JPY)): 2,727,000 (s.d. = 1,440,000), 4,384,000 (869,000), 5,709,000 (1,799,000) and 9,075,000 (5,180,000). In total, 3013 (9.5%) of the households experienced a reduction in household income of 30% or more after the crisis onset. The average annual income for these households was 6,348,000 (s.d. = 6,134,000) Japanese yen before the onset of the economic downturn and 2,631,000 (2,718,000) Japanese yen in 2010 (Table 1). Overall, prevalence of overweight in boys increased from the age of 4 years (Supplementary Information 1), and in girls the general trend was an increase in prevalence that plateaued at age 9 years (Supplementary Information 2); a pattern previously observed in Japanese children.[25–27] Boys and girls in the two lower household income quartiles had consistently higher prevalence of overweight across the years of observation. (Figure 1) Trajectories of overweight prevalence for boys and girls from households with and without a >30% reduction in household income during the economic downturn are shown in Figure 2.

Overweight

Among boys, risk of overweight increased with age, and there was a significant increase in overweight risk after September 2008 (onset of economic downturn) in both models. However, there was no statistical evidence for differences in the trajectories of overweight risk after the onset of the crisis between households experiencing a >30% negative income change during the crisis and those that did not: OR = 1.05 (95% confidence intervals = 0.93–1.17) for the cross term between >30% negative income change and September 2008 (model 2). On the other hand, boys in the two lower income quartiles had a faster increase in overweight risk after September 2008 compared with their counterparts from the highest income quartile (OR for lowest quartile = 1.12 (1.02–1.24); OR for second lowest quartile = 1.15 (1.04–1.26) in model 2). (Table 2)

Girls from households experiencing a >30% income reduction after the crisis onset, had a higher risk of overweight after September 2008 compared with their peers from households with no such income change (OR = 1.23 (1.09–1.38)). Girls in the lower income quartiles had a faster increase in overweight risk after the onset of the economic downturn compared with girls from the highest quartile with the association being more pronounced in the lowest two quartiles (OR for the lowest income quartile = 1.35 (1.23–1.49), OR for the second lowest quartile = 1.25 (1.13–1.38)).

Results did not differ materially in both boys and girls when using >20% income reduction and >10% income reduction cut offs; the OR (95% CI) for the cross term between September 2008 and income reduction was 1.03 (0.93–1.14) for >20% and 1.06 (0.98–1.16) for >10% in boys. The corresponding numbers for girls were 1.14 (1.03–1.27) for >20%, and 1.11 (1.02–1.21) for >10% (Supplementary Information 3). Results were not considerably different when excluding subjects with missing information on covariates (data not shown). Further analyses using alternative time points for calculating income reductions showed that our original analyses (comparing the average household income during 2001–2007 with 2010) showed the most robust results

Q9

Table 1. Population characteristics: Japanese newborns in 2001 in the Longitudinal Survey of Babies in 21st Century, followed up until 2011

	Boys	*Girls*
N (%)	16,403 (51.9)	15,206 (48.1)
Income quartile, n *(%)*		
1 (lowest)	4120 (25.1)	3783 (24.9)
2	4085 (24.9)	3817 (25.1)
3	4119 (25.1)	3783 (24.9)
4 (highest)	4079 (24.9)	3823 (25.1)
>30% negative income change during economic crisis, *n* (%)	1531 (9.3)	1482 (9.8)
>20% negative income change during economic crisis, *n* (%)	2136 (13.0)	2096 (13.8)
>10% negative income change during economic crisis, *n* (%)	3225 (19.7)	3083 (20.3)
Residential area, n *(%)*		
20 designated cities	4209 (25.7)	3868 (25.4)
Other cities	10,640 (64.9)	9908 (65.2)
Rural	1505 (9.2)	1377 (9.1)
Missing	49 (0.3)	53 (0.4)
Mother's age (SD)	30.3 (4.3)	30.3 (4.3)
Father's age (SD)	32.5 (5.4)	32.4 (5.3)
Missing, *n* (%)	299 (1.2)	313 (1.4)
Father's education, n *(%)*		
Junior high school	860 (5.2)	789 (5.2)
High school	6220 (37.9)	5816 (38.3)
Vocational school	2579 (15.7)	2333 (15.3)
Higher education	6332 (38.6)	5896 (38.8)
Missing	412 (2.5)	372 (2.5)
Mother's education, n *(%)*		
Junior high school	418 (2.6)	392 (2.6)
High school	6108 (37.2)	5771 (38)
Vocational school	7120 (43.4)	6420 (42.2)
Higher education	2467 (15)	2373 (15.6)
Missing	290 (1.8)	250 (1.6)
Single parent household, n (%)	266 (1.6)	246 (1.6)
Missing, *n* (%)	5 (0)	5 (0)
Three generation household, *n* (%)	3781 (23.1)	3388 (22.3)

across the models using the different income reduction cut offs of >30, >20 and >10% (Supplementary Information 3).

Underweight

Among boys, prevalence of underweight decreased with age in both models. Models showed higher risk of underweight (adjusted for the decreasing risk by age) after September 2008. No clear evidence of interactions was seen between the crisis onset and income group or between the crisis onset and negative income change during the economic crisis (Table 2).

Among girls, risk of underweight decreased with age and was higher after September 2008 in both models. Girls in the highest income quartile had faster increase in underweight risk after the onset of the economic downturn compared with girls from the lowest quartile (OR for the lowest quartile compared with the highest 0.90 (0.83–0.98); Table 3).

Results did not differ materially in both boys and girls when using >20% income reduction and >10% income reduction cut offs or when excluding subjects with missing information on covariates (data not shown).

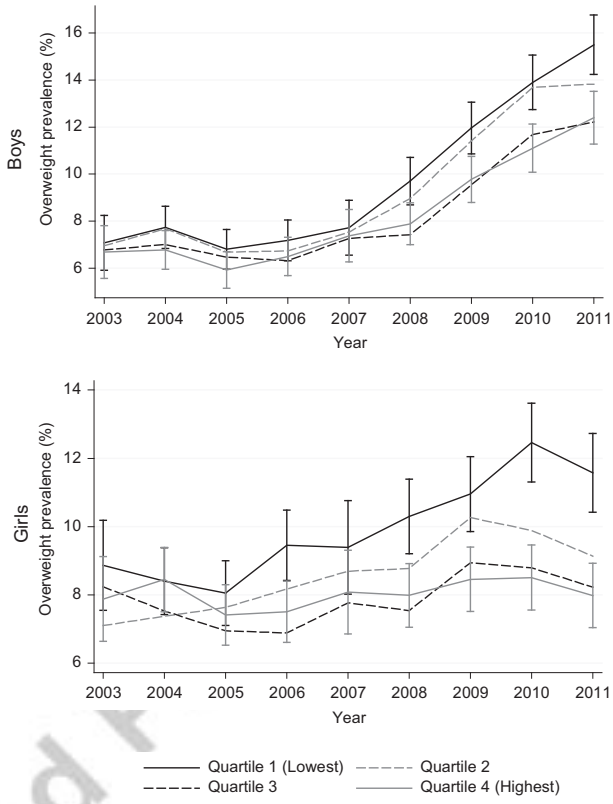

Figure 1. Overweight prevalence with 95% confidence intervals in boys and girls by year and household income quartile.

DISCUSSION

In this nationwide cohort study from Japan, we found that boys and girls from lower income households were at a higher risk of being overweight after the onset of the 2008 economic downturn compared with their peers from higher-income households. Moreover, girls from households experiencing an income reduction in connection to the economic downturn had a higher risk of overweight after the crisis onset than did girls in households without such income reductions. These associations were not seen for underweight.

Although a large number of studies have investigated the relationship between socioeconomic level and childhood overweight and obesity, only a handful have used longitudinal data to assess child BMI in relation to trajectories of socioeconomic status or distress. In a cohort from the United States, children who belonged to low-income groups throughout childhood were more likely to maintain their overweight status and children who became low income during childhood were at higher risk of obesity between 2 and 15 years of age compared with their peers who never were of low-income status.[6] Another US-based study showed that children experiencing downward mobility in household income and stable low income had greater BMI percentile at 15 years of age relative to children in households with more favorable income trajectories.[28] However, a third US report showed that children from households going in and out of poverty had lower risk of becoming overweight between ages 4 and 14 years, compared with children from never poor households.[29]

The observational nature of this study precludes conclusions regarding causality. Although the observed increase in overweight risk after the crisis for girls in household experiencing a negative income change implies that social and economic hardships may

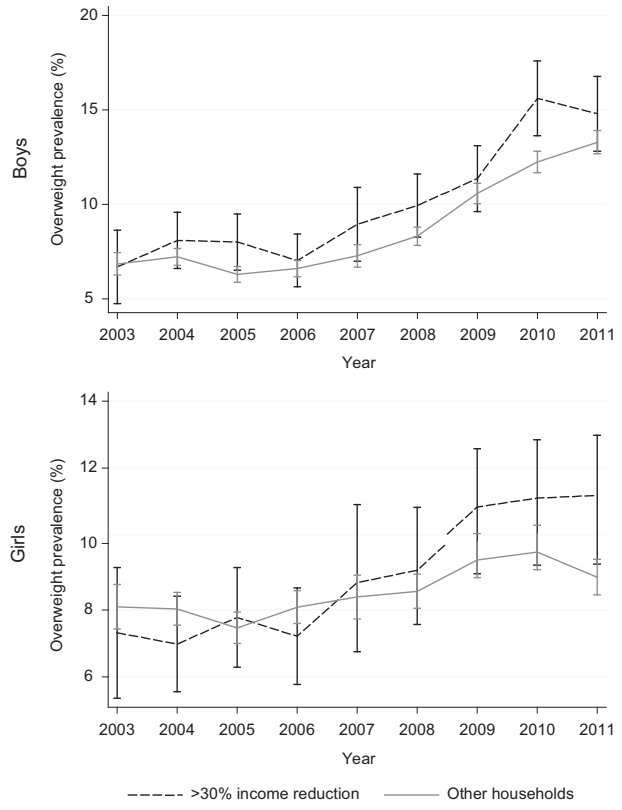

Figure 2. Overweight prevalence by year in boys and girls from households experiencing a >30% income reduction in connection to the global economic crisis and in children from households with no such income reduction.

alter the BMI trajectory of the child, changes in household income may not be regarded as happening at random. Moreover, the divergence in BMI trajectories between the income groups may have occurred in preadolescence regardless of the economic crisis.

If causal, the observed associations could be explained by a number of potential mechanisms. Studies from other high-income countries show that negative life events that may be associated with the economic downturn—including maternal stress, family health problems, financial strain and unstable parental employment—are associated with childhood overweight.[7,8,30] Negative life events in the family may result in a higher food intake, in particular comfort foods,[31,32] which function to alleviate stress at a neurobiological level.[33] Moreover, cuts in the family budget may lead to decreased consumption of fruits and vegetables[34] and increased consumption of fast food.[35] In Japan, longer maternal working hours, in particular among contract workers, have been correlated to increased risk of overweight.[36] These pathways are supported by studies from other countries in which the economic crisis has been linked to worsening nutrition habits and increased mental health problems in children, particularly among those from disadvantaged families.[14] Low-income families may be more vulnerable to the stressors induced by the crisis as they do not have adequate resources to cope with them.

We only found significant associations between income reduction and increased risk of overweight after the crisis onset among girls. The relationship between socioeconomic disadvantage,[3,4] negative life events,[9,21] psychosocial stresses[37,38] and overweight risk may be more pronounced among girls. Eating response to stress is reported more frequently among women.[39,40]

Girls in the highest income groups had a higher risk of underweight after the crisis onset. In Japan underweight prevalence seems to be underpinned by body shape ideals favoring thinness among girls[23,41] and it could be speculated that girls from higher-income households may be aware of body ideals compared with girls from lower income households as they reach preadolescence, and that the diversion of their BMI trajectories coincided with the onset of the economic crisis.

Strengths of this study include repeated measures of weight and height data from a nationwide sample of Japanese children and information about a number of important covariates in the assessment of the relation between the economic downturn and childhood overweight. Our study has limitations, however. Data on household income, and weight and height of the children were based on parents' report. However, a study from Japan found fairly precise parental reports of children's weight status. The sensitivity and specificity for obesity was 83.3–93.3% and 96.3–98.9%, respectively.[42] Accurate reports of children's anthropometric data may also have been facilitated in our study as parents could specify any date of measurement.[43] Furthermore, one-third of the households responding to the initial questionnaire could not be included as required BMI or household income data were not available. Subjects with missing data did not differ from included subjects with respect to sex ($P=0.718$), but had lower annual household income before 2008 (4,716,000 (s.d.=4,290,000) vs 5,842,000 (3,307,000) JPY, $P<0.001$), younger mothers (29.0 vs 30.3 years at birth, $P<0.001$), and were more likely to reside in rural areas in 2001 (20.0% vs 18.8%, $P=0.001$) and to have single parents (3.6% vs 1.6%, $P<0.001$), that is, they were possibly of lower socioeconomic status. There is no apparent reason however, to suspect that subjects with missing data would differ systematically with respect to the relation between the exposures and the outcomes, and thereby cause spurious associations. If anything, the households most severely affected by hardships during the crisis may have been more likely to drop out from the study and also having children gaining more weight. In such a case, a conservative bias may prevail. In addition, all children were born in the same year and followed for ten years, with which we were not able to adjust for the potential variations in the effects across ages. Future studies should test our hypothesis with the data composed of children born in various years.

CONCLUSIONS

Boys and girls from lower income households and girls from households experiencing an income reduction during the global economic crisis starting in 2008, were at increased risk of overweight, but not underweight after the crisis onset. These findings provide yet another argument for policy measures aiming to support households going through financial and social hardships, in particular in the context of the increasing social disparities in Japan.

DISCLAIMER

The study sponsors had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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Table 2. Odds ratio (OR) and 95% confidence interval (CI) for risk of overweight and underweight relative to normal weight in boys

	Overweight		*Underweight*	
	Model 1	*Model 2*	*Model 1*	*Model 2*
	OR (95% CI)	*OR (95% CI)*	*OR (95% CI)*	*OR (95% CI)*
Observations	99,504	99,504	99,504	99,504
Age (years)	1.02 (1.01–1.04)	1.02 (1.01–1.04)	0.86 (0.85–0.87)	0.86 (0.85–0.87)
Household income quartile before 2008				
1 (lowest)	1.15 (1.02–1.30)	0.92 (0.80–1.05)	1.10 (1.01–1.20)	1.11 (1.01–1.21)
2	1.07 (0.95–1.21)	0.95 (0.83–1.08)	1.09 (1.00–1.18)	1.09 (1.00–1.19)
3	1.00 (0.89–1.14)	0.95 (0.84–1.08)	1.02 (0.94–1.11)	1.02 (0.94–1.12)
4 (highest)	1.00 (ref)	1.00 (ref)	1.00 (ref)	1.00 (ref)
>30% negative income change during economic crisis				
No	1.00 (ref)	1.00 (ref)	1.00 (ref)	1.00 (ref)
Yes	1.14 (0.99–1.31)	1.08 (0.93–1.24)	1.06 (0.96–1.17)	1.05 (0.95–1.16)
Step term				
Before September 2008	1.00 (ref)	1.00 (ref)	1.00 (ref)	1.00 (ref)
After September 2008	1.52 (1.39–1.66)	1.52 (1.39–1.67)	1.51 (1.40–1.63)	1.51 (1.40–1.63)
Interaction between income change and step term				
⩽30% negative income change after September 2008	1.00 (ref)	1.00 (ref)	1.00 (ref)	1.00 (ref)
>30% negative income change after September 2008	1.04 (0.93–1.17)	1.05 (0.93–1.17)	0.96 (0.87–1.06)	0.96 (0.87–1.06)
Interaction between income quartile and step term				
Income quartile 1 after September 2008	1.12 (1.02–1.23)	1.12 (1.02–1.24)	1.04 (0.96–1.13)	1.04 (0.96–1.13)
Income quartile 2 after September 2008	1.14 (1.04–1.26)	1.15 (1.04–1.26)	0.98 (0.91–1.07)	0.98 (0.91–1.07)
Income quartile 3 after September 2008	0.99 (0.90–1.09)	0.99 (0.90–1.09)	1.07 (0.99–1.16)	1.07 (0.99–1.16)
Income quartile 4 after September 2008	1.00 (ref)	1.00 (ref)	1.00 (ref)	1.00 (ref)
Father's education				
Junior high school		1.00 (ref)		1.00 (ref)
High school		0.92 (0.79–1.08)		1.04 (0.91–1.19)
Vocational school		0.87 (0.73–1.04)		1.01 (0.87–1.17)
Higher education		0.73 (0.62–0.87)		1.03 (0.90–1.19)
Missing		0.89 (0.62–1.30)		0.97 (0.71–1.33)
Mother's education				
Junior high school		1.00 (ref)		1.00 (ref)
High school		0.72 (0.58–0.88)		0.97 (0.81–1.17)
Vocational school		0.66 (0.54–0.82)		0.95 (0.79–1.15)
Higher education		0.62 (0.50–0.79)		0.94 (0.77–1.15)
Missing		0.80 (0.52–1.25)		1.31 (0.90–1.9)
Single parent household				
No		1.00 (ref)		1.00 (ref)
Yes		1.18 (0.88–1.59)		0.89 (0.68–1.16)
Missing		2.15 (0.45–10.23)		0.40 (0.04–3.72)
Three generation household				
No		1.00 (ref)		1.00 (ref)
Yes		1.39 (1.28–1.51)		0.95 (0.88–1.01)
Residential area				
20 designated cities		1.00 (ref)		1.00 (ref)
Other cities		1.07 (0.98–1.17)		0.93 (0.87–1.00)
Rural		1.11 (0.97–1.27)		0.98 (0.88–1.09)
Missing		1.73 (0.96–3.14)		0.96 (0.57–1.63)
Father's age				
<20 years		1.00 (ref)		1.00 (ref)
21–25 years		2.10 (0.91–4.85)		0.77 (0.43–1.35)
26–30 years		1.77 (0.76–4.11)		0.79 (0.44–1.39)
>30 years		2.10 (0.91–4.88)		0.79 (0.45–1.40)
Missing		2.32 (0.93–5.81)		0.98 (0.51–1.89)
Mother's age				
<20 years		1.00 (ref)		1.00 (ref)
21–25 years		1.08 (0.68–1.73)		1.35 (0.89–2.05)
26–30 years		1.07 (0.67–1.72)		1.24 (0.81–1.89)
>30 years		1.14 (0.71–1.83)		1.22 (0.80–1.86)

A generalized estimating equation model,[24] with an exchangeable correlation structure was used for the analysis.

Table 3. Odds ratio (OR) and 95% confidence interval (CI) for risk of overweight and underweight relative to normal weight in girls

	Overweight		*Underweight*	
	Model 1	*Model 2*	*Model 1*	*Model 2*
	OR (95% CI)	*OR (95% CI)*	*OR (95% CI)*	*OR (95% CI)*
Observations	92,267	92,267	92,267	92,267
Age (years)	0.99 (0.97–1.00)	0.99 (0.97–1.00)	0.94 (0.93–0.95)	0.94 (0.93–0.95)
Household income quartile before 2008				
1 (lowest)	1.14 (1.01–1.29)	0.90 (0.79–1.03)	1.08 (0.99–1.18)	1.09 (0.99–1.21)
2	1.00 (0.88–1.13)	0.86 (0.76–0.98)	1.10 (1.01–1.20)	1.10 (1.00–1.22)
3	0.91 (0.81–1.04)	0.85 (0.74–0.96)	1.05 (0.96–1.15)	1.05 (0.95–1.15)
4 (highest)	1.00 (ref)	1.00 (ref)	1.00 (ref)	1.00 (ref)
>30% negative income change during economic crisis				
No	1.00 (ref)	1.00 (ref)	1.00 (ref)	1.00 (ref)
Yes	0.98 (0.84–1.13)	0.92 (0.80–1.07)	0.96 (0.86–1.07)	0.96 (0.86–1.07)
Step term				
Before September 2008	1.00 (ref)	1.00 (ref)	1.00 (ref)	1.00 (ref)
After September 2008	1.06 (0.97–1.17)	1.06 (0.97–1.17)	1.50 (1.39–1.61)	1.50 (1.39–1.61)
Interaction between income change and step term				
⩽30% negative income change after September 2008	1.00 (ref)	1.00 (ref)	1.00 (ref)	1.00 (ref)
>30% negative income change after September 2008	1.22 (1.08–1.37)	1.23 (1.09–1.38)	1.00 (0.91–1.11)	1.00 (0.91–1.11)
Interaction between income quartile and step term				
Income quartile 1 after September 2008	1.35 (1.22–1.49)	1.35 (1.23–1.49)	0.90 (0.83–0.98)	0.90 (0.83–0.98)
Income quartile 2 after September 2008	1.25 (1.13–1.38)	1.25 (1.13–1.38)	0.94 (0.87–1.02)	0.94 (0.87–1.02)
Income quartile 3 after September 2008	1.18 (1.07–1.31)	1.18 (1.07–1.31)	0.99 (0.92–1.08)	0.99 (0.92–1.08)
Income quartile 4 after September 2008	1.00 (ref)	1.00 (ref)	1.00 (ref)	1.00 (ref)
Father's education				
Junior high school		1.00 (ref)		1.00 (ref)
High school		0.93 (0.78–1.10)		1.04 (0.90–1.20)
Vocational school		0.90 (0.74–1.09)		1.11 (0.95–1.30)
Higher education		0.79 (0.65–0.95)		1.05 (0.90–1.22)
Missing		0.98 (0.64–1.50)		0.92 (0.65–1.31)
Mother's education				
Junior high school		1.00 (ref)		1.00 (ref)
High school		0.63 (0.51–0.78)		0.88 (0.73–1.07)
Vocational school		0.51 (0.41–0.64)		0.89 (0.73–1.08)
Higher education		0.47 (0.36–0.60)		0.86 (0.70–1.07)
Missing		0.58 (0.35–0.96)		1.22 (0.80–1.84)
Single parent household				
No		1.00 (ref)		1.00 (ref)
Yes		1.06 (0.75–1.50)		0.97 (0.73–1.29)
Missing		1.38 (0.13–14.13)		5.17 (1.53–17.49)
Three generation household				
No		1.00 (ref)		1.00 (ref)
Yes		1.27 (1.15–1.39)		0.95 (0.88–1.02)
Residential area				
20 designated cities		1.00 (ref)		1.00 (ref)
Other cities		1.17 (1.06–1.29)		0.92 (0.86–0.99)
Rural		1.41 (1.21–1.63)		0.86 (0.76–0.97)
Missing		0.77 (0.32–1.85)		0.79 (0.46–1.34)
Father's age				
<20 years		1.00 (ref)		1.00 (ref)
21–25 years		0.85 (0.39–1.85)		0.55 (0.30–1.00)
26–30 years		0.94 (0.43–2.08)		0.62 (0.34–1.13)
>30 years		1.11 (0.50–2.46)		0.63 (0.34–1.14)
Missing		0.80 (0.32–1.98)		0.59 (0.29–1.18)
Mother's age				
<20 years		1.00 (ref)		1.00 (ref)
21–25 years		1.22 (0.69–2.18)		1.53 (0.93–2.52)
26–30 years		1.14 (0.63–2.04)		1.35 (0.81–2.23)
>30 years		1.24 (0.69–2.23)		1.32 (0.80–2.19)

A generalized estimating equation model,[24] with an exchangeable correlation structure was used for the analysis.

AUTHOR CONTRIBUTIONS

NK, PU and TF conceived the study. PU and KN conducted the statistical analysis. PU, NK and TF wrote the manuscript. KN is the guarantor.

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Global trends and projections for tobacco use, 1990–2025: an analysis of smoking indicators from the WHO Comprehensive Information Systems for Tobacco Control

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Summary

Background **Countries have agreed on reduction targets for tobacco smoking stipulated in the WHO global monitoring framework, for achievement by 2025. In an analysis of data for tobacco smoking prevalence from nationally representative survey data, we aimed to provide comprehensive estimates of recent trends in tobacco smoking, projections for future tobacco smoking, and country-level estimates of probabilities of achieving tobacco smoking targets.**

Methods **We used a Bayesian hierarchical meta-regression modelling approach using data from the WHO Comprehensive Information Systems for Tobacco Control to assess trends from 1990 to 2010 and made projections up to 2025 for current tobacco smoking, daily tobacco smoking, current cigarette smoking, and daily cigarette smoking for 173 countries for men and 178 countries for women. Modelling was implemented in Python with DisMod-MR and PyMC. We estimated trends in country-specific prevalence of tobacco use, projections for future tobacco use, and probabilities for decreased tobacco use, increased tobacco use, and achievement of targets for tobacco control from posterior distributions.**

Findings **During the most recent decade (2000–10), the prevalence of tobacco smoking in men fell in 125 (72%) countries, and in women fell in 156 (88%) countries. If these trends continue, only 37 (21%) countries are on track to achieve their targets for men and 88 (49%) are on track for women, and there would be an estimated 1·1 billion current tobacco smokers (95% credible interval 700 million to 1·6 billion) in 2025. Rapid increases are predicted in Africa for men and in the eastern Mediterranean for both men and women, suggesting the need for enhanced measures for tobacco control in these regions.**

Interpretation **Our findings show that striking between-country disparities in tobacco use would persist in 2025, with many countries not on track to achieve tobacco control targets and several low-income and middle-income countries at risk of worsening tobacco epidemics if these trends remain unchanged. Immediate, effective, and sustained action is necessary to attain and maintain desirable trajectories for tobacco control and achieve global convergence towards elimination of tobacco use.**

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Introduction

Tobacco control is a global health priority. The WHO Framework Convention on Tobacco Control, which entered into force in 2005, formalised global commitment,[1] and so far has been ratified by 180 parties.[2] However, country-specific progress varies substantially, with very high prevalence of smoking among both men and women in many countries.[3] WHO estimates that about 6 million people worldwide die each year from causes attributed to smoking, with most of these deaths occurring in low-income and middle-income countries.[4] The 2011 UN political declaration on non-communicable diseases provided additional impetus both for urgent and sustained control of tobacco use and for preventive action against other risk factors for non-communicable diseases.[5] In 2013, the World Health Assembly endorsed the WHO global monitoring framework for non-communicable diseases and an associated voluntary global target of a 30% relative reduction in tobacco use worldwide among people aged 15 years or older by 2025 (with 2010 levels as baseline). This target was officially agreed on by WHO member states on the basis of experience from countries that had successfully implemented at the highest level of achievement at least three of the demand reduction measures outlined in the WHO Framework Convention, and will account for varying initial starting points for tobacco control in assessment of national progress.[6] This target was endorsed at the Sixth Meeting of the Convention of Parties in Moscow in October, 2014.[7] Monitoring of progress towards these targets will be of enormous benefit to individual

countries because it will assist them in taking necessary corrections or new actions to reduce consumption of tobacco products.

Although some country-specific estimates of prevalence and trends in tobacco smoking are available, a comprehensive and consistent set of estimates—combining historical trends and the most up-to-date data with projections of the future burden of tobacco use—is needed for as many countries as possible. The WHO Reports on the Global Tobacco Epidemic regularly provide specific-year estimates for smoking prevalence, but do not provide changes over time or levels of uncertainty around estimates.[3] The Institute for Health Metrics and Evaluation recently estimated prevalence trends from 1980 to 2012, but only for one measure, daily smoking.[8] Neither of these studies projected trends in smoking prevalence nor assessed target achievement.[3,8]

The tobacco epidemic proceeds through distinct stages,[9] which can be affected by policy interventions;[10] because many countries with mature tobacco epidemics have now implemented extensive control policies under the 2003 Framework Convention,[3] trends from the past 10 years can serve as a useful guide for future strategies. Synthesis of existing trend data by region and country, with projections, can provide a useful instrument to assist development for tobacco control. We aimed to provide a comprehensive and consistent set of trend estimates for four tobacco use indicators from 2000 to 2010, and projections to 2025, with target achievement probabilities under the WHO global monitoring framework, using the most comprehensive and up-to-date nationally representative data available.

Methods

Study design and data sources

We did a systematic assessment of trends for four tobacco smoking indicators—current tobacco smoking, daily tobacco smoking, current cigarette smoking, and daily cigarette smoking—for 178 countries from 1990 to 2014 with baseline projections to 2025. The four indicators we modelled represent important characteristics of frequency and product type, and are intended to capture the full diversity of tobacco smoking for which data are available. We report estimates for prevalence and trends in current tobacco smoking, incorporating daily smoking and occasional smoking[11] of any type of smoked tobacco.

We obtained data about tobacco use prevalence from the WHO Comprehensive Information Systems for Tobacco Control. This database encompasses major, internationally standardised data sources that report tobacco use of any kind; all data sources used are population-based surveys in the public domain. We investigated data availability and quality for all 194 WHO member states. The primary datasets included reports of survey estimates submitted to the WHO Framework Convention on Tobacco Control Secretariat, surveys such as the Global Adult Tobacco Survey[12] operated as part of the WHO Global Tobacco Surveillance System, and major nationally representative health surveys such as the World Health Survey,[13] Demographic and Health Surveys, the Behavioral Risk Factor Surveillance System,[14] and the WHO STEPwise surveys.[15] Data quality control at the time of collection was done by the WHO Comprehensive Information Systems for Tobacco Control unit, and discrepancies (eg, zero values of major prevalence estimates, higher reported prevalence for women than for men, prevalence more than 60%, or inconsistencies in different indicators) were investigated with country representatives before finalisation in the database. Details about the identification process for data sources and about data entry, reconciliation, and quality checking procedures are provided in the appendix.

For the **Demographic and Health Surveys** see http://www.measuredhs.com/

See **Online** for appendix

A data source was included if it provided prevalence estimates from country surveys for one or more of the four tobacco use indicators used in this study; involved randomly selected participants representative of the general population; and was officially recognised by the national health authority. A data source was excluded if it was earlier than 1990, was not nationally representative (eg, urban or rural only, geographic or political subdivision, subpopulations such as students only), or if the maximum age of target participants was younger than 15 years. The dataset for this analysis encompassed 896 surveys in 180 countries covering the period 1990 to 2014, amounting to 26 153 datapoints specific to country, year, sex, and age.

Outcome definitions

Tobacco refers to all forms of smoked tobacco encountered in the surveys including, but not limited to, cigarette, cigar, pipe, and water pipe. Cigarette included any kind of cigarette such as manufactured, roll-your-own, or local variants (eg, bidis in India or kreteks in Indonesia). Current refers to smoking at least once in the 30 days before the survey. Daily refers to smoking at least once per day during the same 30 day period.[16] Almost all surveys in the dataset excluded experimental smokers when reporting prevalence of current and daily smoking. Current tobacco smoking is an important indicator because it can more sensitively detect trends among groups with historically low prevalence of smoking (eg, women[17] and late teenagers[18]) than can the other component tobacco use indicators; we focused on this outcome in this study.

Statistical analysis

For analytic purposes, we categorised countries into 21 regions representing tobacco epidemiology and geography. These groups combined tobacco use patterns and control history with the UN geoscheme subregions.[3,19] Details of the country groupings are provided in the appendix.

The analytic approach for this study needed to address data scarcity for some countries, non-standard age categories, and information for four tobacco smoking

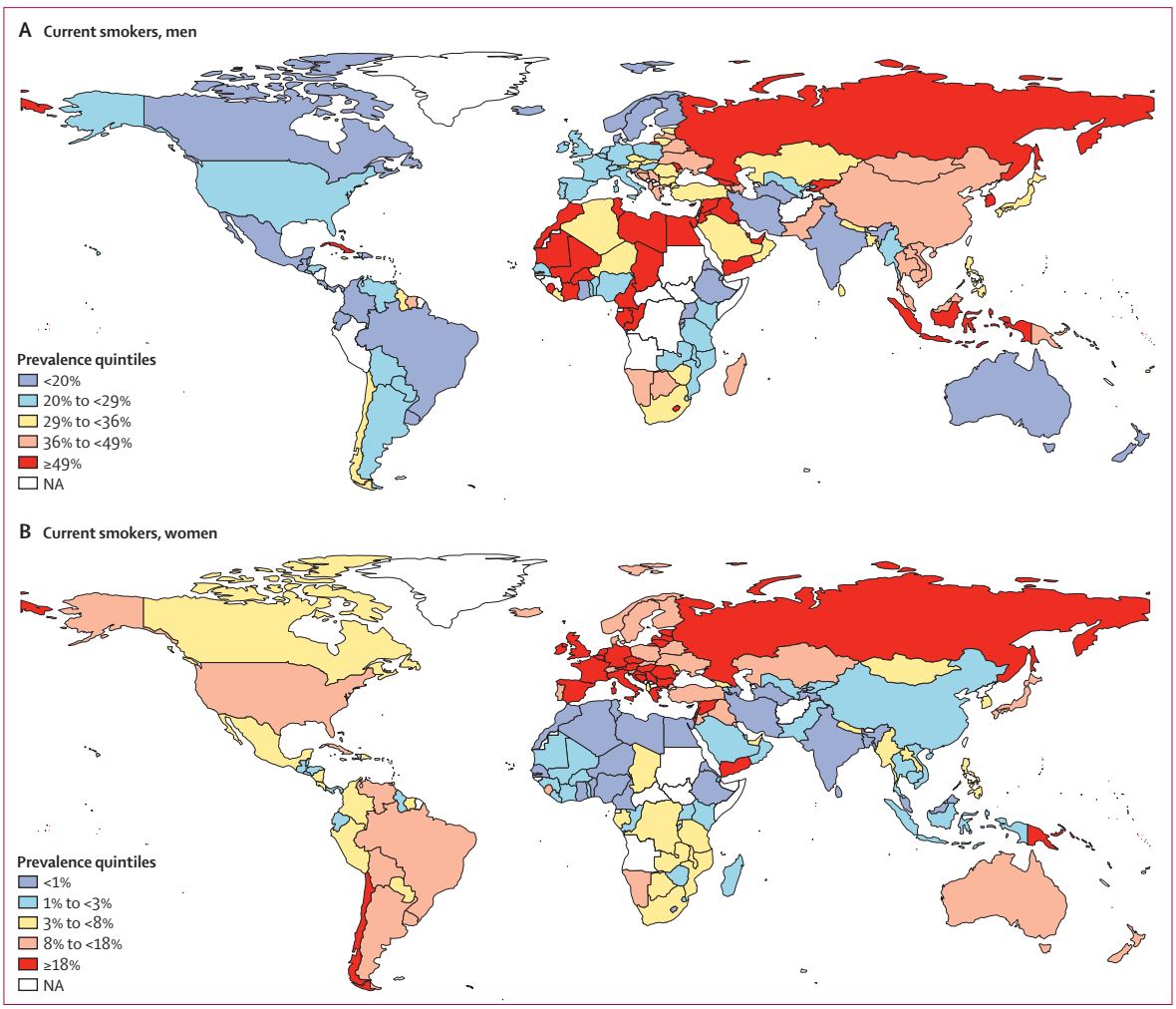

Figure 1: **Estimated prevalence of current tobacco smoking in 2025**
Figure shows age-standardised mean estimates for individuals aged 15 years or older. NA=not available.

indicators, with consistency constraints between indicators such that current tobacco smoking served as the prevalence envelope for daily tobacco smoking and current cigarette smoking, which in turn were both greater than or equal to daily cigarette smoking. To overcome these challenges, we developed a Bayesian hierarchical meta-regression model, combining observed data with additional prior assumptions to derive posterior distributions of the quantities of interest. This multistage modelling approach handles these problems by first identifying trends at the regional level, and then using these trends to build priors for the coefficients in subsequent country-level models, enabling supplementation of scarce country data with regional information. We used a piecewise linear spline to model age-specific prevalence in the population aged 15 years or older with breakpoints per 10-year age group chosen in consultation with WHO tobacco and statistical experts. This is a flexible approach that captures diversity and detail in age patterns in different countries.

We fitted the model over two periods, 1990–2000 and 2000–10, and used a time–period interaction term to allow for potential shifts due to country-level changes in time-varying factors (eg, implementation of tobacco control measures). Indicator coefficients with constraints in the form of priors enabled simultaneous and consistent estimation of the different indicators of tobacco use. Details about the model equations, a directed acyclic graph for the Bayesian hierarchical structure, and detailed information about prior assumptions are provided in the appendix. We did model fitting separately for men and women, applying Markov-chain Monte Carlo methods implemented in the Python programming language.[20] We used the DisMod-MR[21] package (a Bayesian modelling instrument) to handle non-standard age categories, model specification, and meta-regression, and the PyMC package[22] for Markov-chain Monte Carlo simulation. We obtained posterior distributions for all outcomes of interest, enabling the

calculation of probabilities of decrease or increase in prevalence of tobacco use, and probabilities of reaching tobacco control targets by 2025.

We fitted separate models by country and sex to allow for potentially diverging trends between sexes. We obtained trend estimates for the period 1990–2000 and 2000 onwards, carrying the post-2000 trend forward to provide projections for all four indicators to 2025. 1000 draws per year of age were generated from the resulting posterior distributions, and we used the WHO standard population[23] to obtain aggregated, age-standardised prevalence for ages 15 years or older. We estimated means and obtained 95% credible intervals from the 2·5% and 97·5% percentiles of the distributions of these replicates. We obtained numbers of smokers by multiplying prevalence and population estimates.[24] Quintiles of mean prevalence were calculated for 2010 and 2025. We calculated percentage changes from 2010 to 2025 and posterior probabilities of reduction, increase, and target achievement from these distributions. A posterior probability of reduction of 95% or greater means that at least 95% of the simulated percentage changes are below zero.

We used autocorrelation plots to assess model convergence, tested for predictive accuracy using root-mean-squared errors and coverage of 95% posterior predictive intervals, and checked for robustness in out-of-sample prediction by holdout cross-validation. We used the Bayesian information criterion to assess interaction terms.[25]

Role of the funding source

The funders had no role in the design, implementation, analysis, or writing of the study, or choice of journal. The corresponding author had full access to all the data and had final responsibility for the decision to submit for publication.

Results

We generated estimates about current tobacco smoking for 173 countries for men and 178 countries for women. The appendix contains country-specific estimates of prevalence in 2010 and 2025; relative percentage changes and posterior probabilities of reduction, increase, and target achievement; and prevalence quintiles in 2010 and 2025 by WHO region and income categories. Figure 1 shows maps of predicted prevalence quintiles in 2025. The first quintile represents countries with the lowest prevalences, whereas the fifth quintile represents those with the highest prevalences. Prevalence estimates in 2000 ranged from less than 25% in the first quintile to 56% or greater in the fifth quintile for men, and from less than 3% in the first quintile to 27% or greater in the fifth quintile for women. For men, most countries in the first quintile (21 [57%] countries) were low-income or middle-income countries in Africa, with the fifth quintile concentrated in Europe and the western Pacific. For women, most countries in the first quintile were low-income and middle-income countries from diverse geographies (21 [84%] countries), including 14 (45%) African nations. Conversely, countries in the fifth quintile were concentrated mainly in Europe and the western Pacific. By 2010, estimated prevalences ranged from less than 24% in the first quintile to 48% or greater in the fifth quintile for men, and from less than 2% in the first quintile to 22% or greater in the fifth quintile for

	Number of countries	Direction of trend, 2000–10		≥95% probability, 2010–25	
		Decrease	Increase	Decrease	Increase
Men					
Low-income or middle-income countries					
AFRO	40	15 (44%)	25 (56%)	1 (5%)	15 (37%)
AMRO	23	22 (57%)	1 (1%)	13 (54%)	0
EMRO	13	2 (14%)	11 (73%)	0	2 (2%)
EURO	17	16 (27%)	1 (<1%)	4 (12%)	0
SEARO	9	7 (86%)	2 (14%)	3 (80%)	0
WPRO	20	20 (89%)	0	1 (5%)	0
Subtotal	122	82 (80%)	40 (20%)	22 (40%)	17 (5%)
High-income countries					
AFRO	0	0	0	0	0
AMRO	8	7 (42%)	1 (<1%)	3 (39%)	0
EMRO	6	0	6 (13%)	0	4 (5%)
EURO	31	31 (73%)	0	15 (25%)	0
SEARO	0	0	0	0	0
WPRO	6	5 (11%)	1 (<1%)	3 (8%)	0
Subtotal	51	43 (94%)	8 (6%)	21 (56%)	4 (2%)
Total for men	173	125 (83%)	48 (17%)	43 (43%)	21 (5%)
Women					
Low-income or middle-income countries					
AFRO	42	36 (88%)	6 (12%)	21 (50%)	0
AMRO	25	25 (60%)	0	24 (60%)	0
EMRO	13	7 (74%)	6 (18%)	6 (74%)	0
EURO	18	16 (27%)	2 (1%)	6 (11%)	0
SEARO	9	9 (100%)	0	9 (100%)	0
WPRO	20	20 (88%)	0	7 (87%)	0
Subtotal	127	113 (96%)	14 (4%)	73 (88%)	0
High-income countries					
AFRO	0	0	0	0	0
AMRO	8	8 (40%)	0	7 (38%)	0
EMRO	6	1 (4%)	5 (3%)	0	0
EURO	31	27 (56%)	4 (16%)	9 (16%)	0
SEARO	0	0	0	0	0
WPRO	6	6 (12%)	0	4 (9%)	0
Subtotal	51	42 (88%)	9 (12%)	20 (51%)	0
Total for women	178	155 (95%)	23 (5%)	93 (81%)	0

Data are n, in which n refers to number of countries, or n (%), in which n refers to number of countries and % refers to the proportion of the regional population covered. Table shows data for individuals aged 15 years or older; income categories are from The World Bank. AFRO=WHO African Region. AMRO=WHO Region of the Americas. EMRO=WHO Eastern Mediterranean Region. EURO=WHO European Region. SEARO=WHO Southeast Asian Region. WPRO=WHO Western Pacific Region.

Table 1: **Relative change in age-standardised prevalence of current smoking by WHO region**

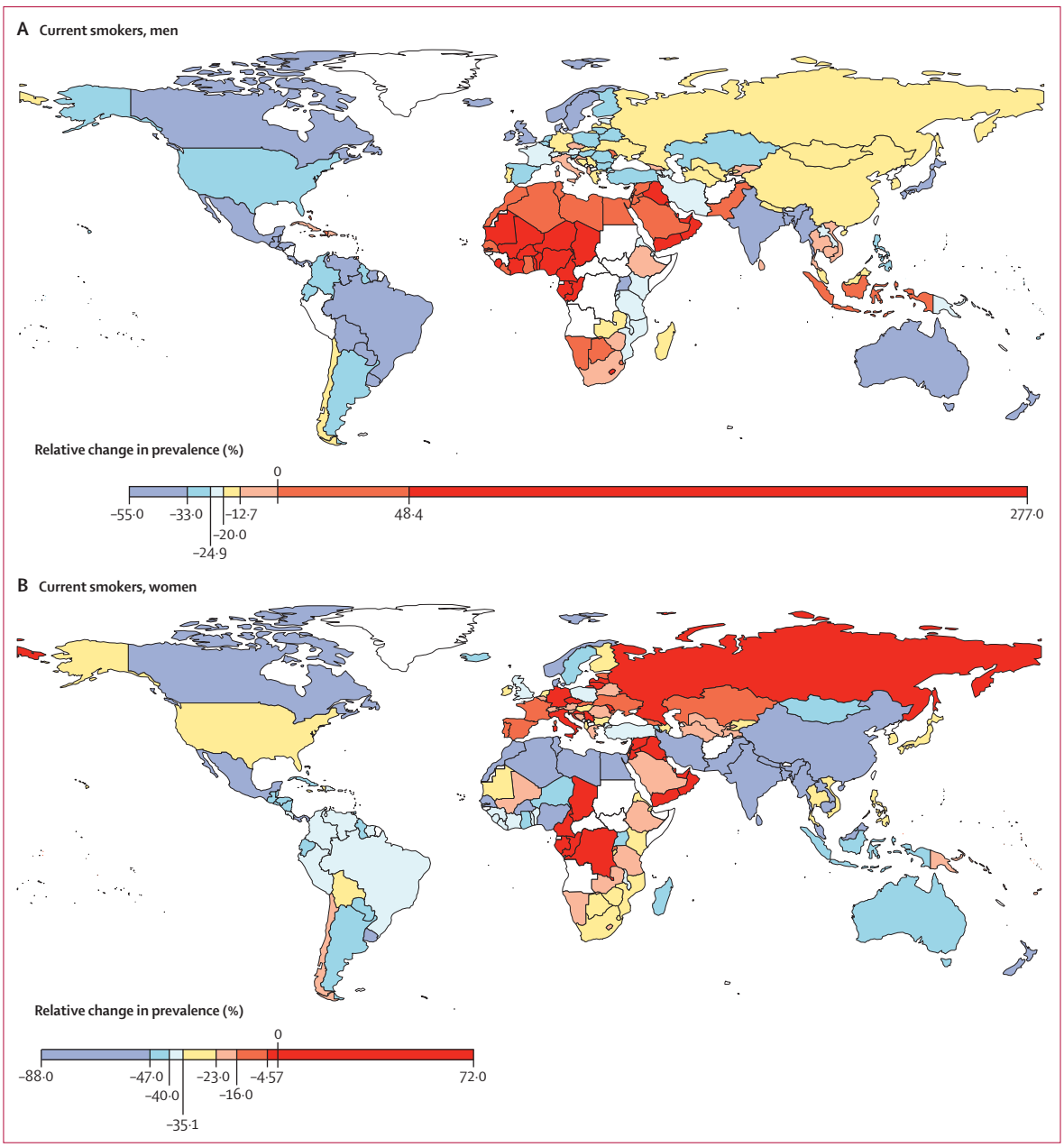

Figure 2: **Relative change in prevalence of current tobacco smoking between 2010 and 2025**
Figure shows age-standardised mean estimates for individuals aged 15 years or older. NA=not available.

women. For men, 24 (67%) countries in the first quintile were low-income or middle-income countries in Africa and the Americas, with several African nations increasing in prevalence. The composition of the fifth quintile remained similar to those in 2000. For women, patterns in the first and the fifth quintiles also remained similar to those in 2000. Our estimates of trends between 2000 and 2010 suggested that tobacco control efforts have been successful, with 125 (72%) countries for men and 155 (87%) countries for women showing any level of decrease to 2010.

If recent trends remain unchanged, there will be an estimated 1·1 billion current smokers (95% credible interval 700 million to 1·6 billion) in 2025. We project that the highest smoking quintile among men will shift from low-income and middle-income countries in Europe and the western Pacific to those in Africa and the eastern Mediterranean, suggesting a rapidly growing epidemic of tobacco smoking in this region and a major additional burden of non-communicable disease in these countries. For women, 2025 prevalence patterns will remain similar to those at baseline, with

the first quintile mostly consisting of low-income and middle-income countries from diverse geographies including 15 (43%) African nations, with the fifth quintile concentrated in Europe and the western Pacific.

Table 1 summarises patterns in trend estimates from 2000 to 2010 and probabilities of reduction and increase in prevalence from 2010 to 2025 by region and income category. Corresponding relative percentage changes from 2010 to 2025 are mapped in figure 2. From 2000 to 2010, 125 (72%) countries experienced decreases in prevalence for men, compared with 155 (87%) countries for women. If such trends continue, only 43 (25%) countries for men and 93 (52%) countries for women will have 95% or greater probability of decrease from 2010 to 2025, and 21 (12%) countries will have 95% or greater probability of increase among men over the same period. Decreases are projected for most countries in almost all regions except Africa for men and the eastern Mediterranean for both men and women. We noted high (≥95%) probabilities of decrease for most countries in the Americas for both men and women. By contrast, high probabilities of increase were estimated for about a third of countries in Africa and the eastern Mediterranean for men. For European men, 15 (48%) high-income countries had a high probability of reduction, compared with only four (24%) low-income or middle-income countries, suggesting that within-region income inequalities remain an issue in tobacco control.

Scatterplots of relative percentage changes from 2010 to 2025 against baseline prevalence in 2010 are provided in figure 3, with countries categorised according to probabilities of achieving tobacco control targets. Only 37 (21%) countries are on track to achieve their targets for men and 88 (49%) countries are on track for women. Only three (2%) countries for men and 22 (12%) countries for women had high probabilities (≥95%) of target achievement. We estimated relative prevalence increases of greater than 100% for men in seven (4%) countries in Africa and the eastern Mediterranean. We noted low (<5%) target achievement probabilities for several countries for both sexes. Geographic representations of target achievement probabilities are shown in figure 4 and summaries by WHO region and World Bank income classification are shown in table 2. Low-income and middle-income settings had higher proportions (38 [31%] *vs* eight [16%]) of countries with low target achievement probabilities for men and high-income settings had higher proportions (12 [24%] *vs* 12 [9%]) of countries with low target achievement probabilities for women, suggesting continued growth of tobacco smoking among men in low-income countries and persistence among women in high-income countries.

The results for all indicators by country are available on the WHO website.

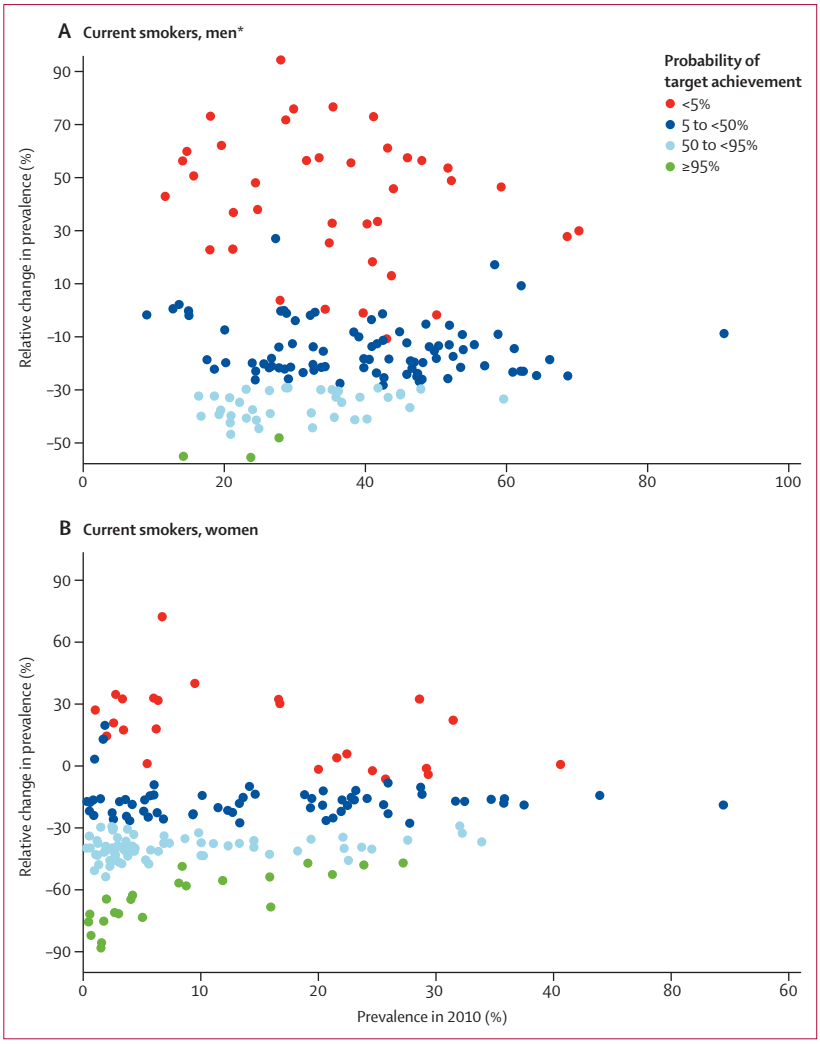

Figure 3: **Relative change in prevalence of current tobacco smoking between 2010 and 2025, versus baseline prevalence and probabilities of target achievement**
*Seven countries with more than 100% relative change not shown.

Discussion

This analysis of nationally representative survey data provides a comprehensive set of comparable and consistent estimates and projections for four tobacco use indicators and target achievement probabilities under the global monitoring framework for non-communicable diseases; the use of the most up-to-date data and a comprehensive modelling process enabled information from multiple indicators to be used directly in a single flexible model (panel). We estimated trends in prevalence of tobacco smoking from 1990 to 2010 using data available until June, 2014, and made projections to 2025 for 178 countries for women and 173 countries for men. We also estimated mean percentage changes in prevalence between 2010 and 2025 with posterior probabilities of reduction, increase, and target achievement. We engaged with national authorities to ensure a comprehensive database, used

For the **results of all indicators by country** see http://www.who.int/tobacco/publications/surveillance/en/

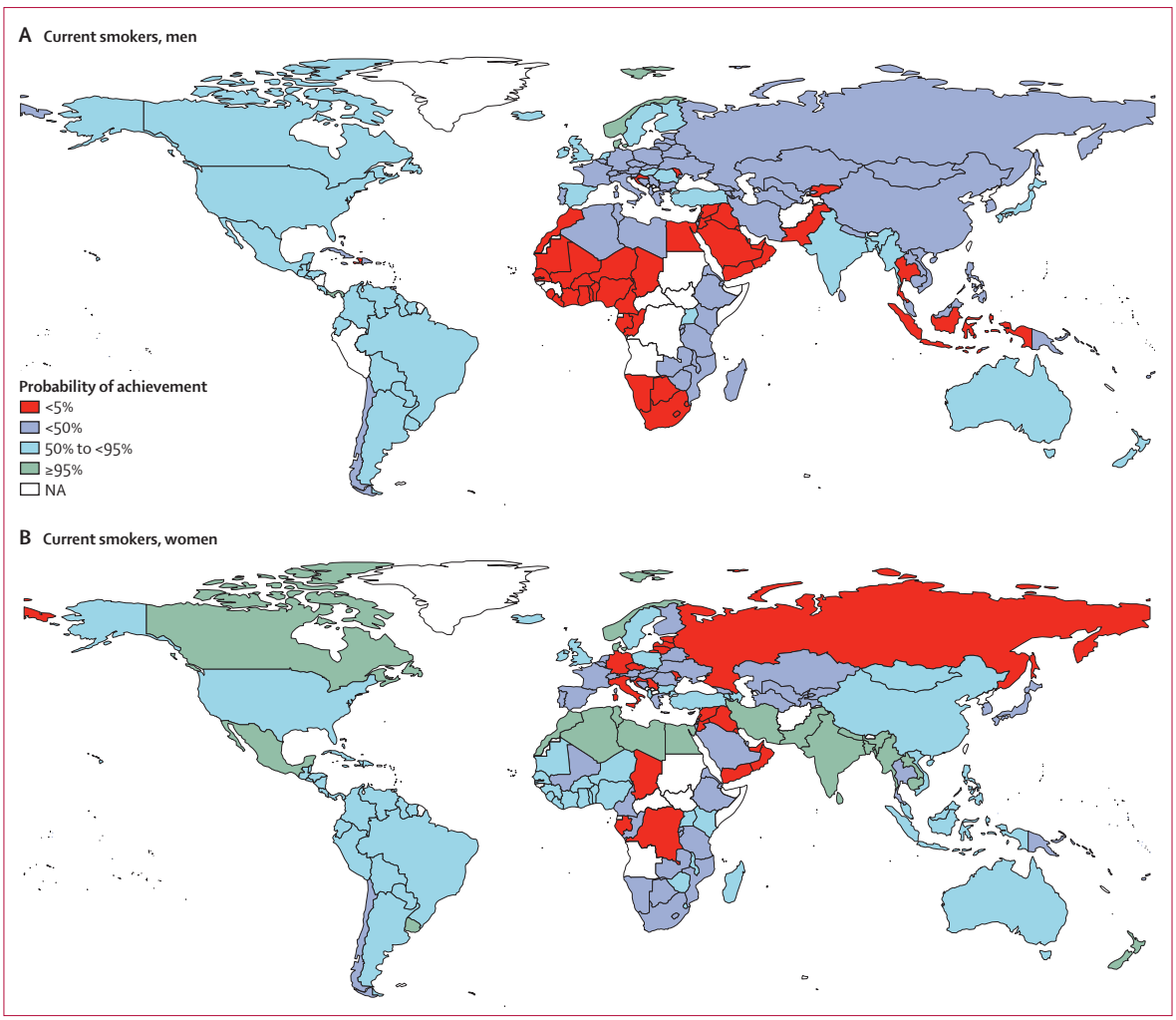

Figure 4: **Probability of 30% reduction in tobacco use by 2025**
Figure shows probability of countries achieving a 30% relative reduction compared with prevalence levels in 2010, assuming current trends continue.

the latest available survey data, and consulted with individual countries regarding discrepancies as part of the WHO global estimation process.

We noted wide variation in baseline prevalence, suggesting differences in tobacco epidemic stages and in control efforts between countries. Our prevalence projections showed that such disparities are likely to persist. Countries already at mature stages of the smoking epidemic at baseline, which are projected to retain high prevalence in 2025, need immediate and effective implementation or strengthening of measures for smoking cessation, avoidance of relapse, and deterrence of initiation. Countries where the smoking epidemic has not gained a foothold or is in its early stages are mostly in low-income or middle-income countries where tobacco control might not be a top priority because of scarce resources to address pressing health concerns. However, these situations present opportunities for these countries' governments, in cooperation with the international community, to invest in or strengthen cost-effective preventive strategies before tobacco companies establish and expand their markets.

Many countries will not achieve the 30% reduction target if current trends remain unchanged, and more effort is needed to attain or to maintain desirable trajectories. The demand reduction measures in the WHO Framework Convention on Tobacco Control (known as WHO MPOWER measures) serve as a good starting point. Aimed to assist countries with implementation of the framework, these measures consist of six broad implementation strategies: "monitor tobacco use and prevention policies, protect people from tobacco smoke, offer help to quit tobacco use, warn about the dangers of tobacco, enforce bans on tobacco advertising, promotion and sponsorship, and raise taxes on tobacco".[31] Although the WHO Framework Convention on Tobacco Control has been ratified by 180 parties to date,[2] completeness of implementation of the MPOWER

measures varies greatly across countries.[3] The importance of immediate and extensive MPOWER implementation is exemplified by Turkey, which we project will achieve a greater than 30% reduction in current smoking prevalence by 2025, representing an annual decrease of greater than 2·0% over 15 years. Turkey ratified the Framework Convention on Tobacco Control in 2004, and is the only country to have been assessed by WHO to have implemented MPOWER measures at the highest level. Turkey has experienced substantial reductions in tobacco use prevalence since then. If sustained, this trend would be sufficient to attain the 2% annual reduction over 15 years required by the target. However, even countries on track towards target achievement should be vigilant and exert efforts to maintain desirable trajectories. Norway provides an example of the importance of vigilance to maintain tobacco control efforts. We estimate that Norway will achieve a 45% reduction in current smoking prevalence, representing a 3·0% annual decrease over 15 years, with high probabilities (>95%) for both men and women. After waning prioritisation of tobacco control in the 1980s and stalled prevalence reductions, tobacco use reductions were again achieved after reinvigoration of the national programme for tobacco control in the 1990s, and have been maintained.[32] Norway was able to achieve a 30% reduction in tobacco use within a decade,[33] and its national tobacco control strategy continues to evolve.[34] These countries offer lessons in effective tobacco control, and show the potential value of the MPOWER package for countries that we have identified as at risk of increasing or static trends in current smoking prevalence.

Although tobacco control strategies are at the forefront of changes in tobacco use prevalence, smoking trends might also result from other factors. Similar to Norway, Sweden is projected to achieve 37% or greater relative reduction in current smoking prevalence, representing annual decreases over 15 years for both men and women of roughly 2·4%. In both countries, however, consumption of smokeless oral tobacco (snus) has been increasing in recent years.[35–37] Although snus has been suggested to help smoking cessation, its health effects remain controversial and debate about its role as a tobacco cessation strategy is ongoing.[35,38,39] Some portion of Norway and Sweden's success might therefore represent substitution to unmeasured forms of tobacco use rather than cessation, and for any country the particular cultural context of tobacco use remains an important consideration in interpretation of our model outputs.

Our study also had several limitations. First, our study relied on self-reported data with the potential for reporting bias that could vary across settings and over time. However, validation exercises with biomarkers in high-income settings have shown self-reported smoking behaviour to have high sensitivities (>90%),[40,41] and cross-country surveys in low-income and middle-income countries use scientific and evidence-based protocols to ensure comparability across settings and over time.[42] Although residual variability due to differences in data sources might persist despite quality control efforts, these factors were addressed to the extent feasible by prior specifications in the statistical model. Second, the need to calculate projections necessarily placed restrictions on the model choices. Although use of a functional form in the model enabled projection beyond

	Number of countries	Projected to achieve target	Probability of achieving target by 2025			
			<5%	5 to <50%	50 to <95%	≥95%
Men						
Low-income or middle-income countries						
AFRO	40	1 (5%)	24 (51%)	15 (44%)	1 (5%)	0
AMRO	23	16 (55%)	1 (1%)	6 (3%)	15 (54%)	1 (<1%)
EMRO	13	0	9 (70%)	4 (3%)	0	0
EURO	17	2 (9%)	2 (<1%)	12 (15%)	3 (12%)	0
SEARO	9	3 (80%)	2 (17%)	4 (17%)	3 (80%)	0
WPRO	20	2 (<1%)	0	18 (89%)	2 (<1%)	0
Subtotal	122	24 (38%)	38 (20%)	59 (42%)	24 (38%)	1 (<1%)
High-income countries						
AFRO	0	0	0	0	0	0
AMRO	8	2 (4%)	0	5 (2%)	3 (39%)	0
EMRO	6	0	6 (13%)	0	0	0
EURO	31	8 (16%)	1 (<1%)	21 (55%)	7 (17%)	2 (1%)
SEARO	0	0	0	0	0	0
WPRO	6	3 (8%)	1 (<1%)	2 (3%)	3 (8%)	0
Subtotal	51	13 (25%)	8 (6%)	28 (43%)	13 (50%)	2 (<1%)
Total for men	173	37 (35%)	46 (17%)	87 (42%)	37 (40%)	3 (<1%)
Women						
Low-income or middle-income countries						
AFRO	42	22 (50%)	4 (9%)	15 (36%)	21 (50%)	2 (5%)
AMRO	25	25 (60%)	0	0	24 (48%)	1 (13%)
EMRO	13	6 (74%)	6 (18%)	1 (<1%)	0	6 (74%)
EURO	18	5 (10%)	2 (1%)	11 (16%)	5 (10%)	0
SEARO	9	8 (96%)	0	1 (4%)	2 (14%)	6 (82%)
WPRO	20	6 (82%)	0	13 (<1%)	5 (86%)	2 (1%)
Subtotal	127	72 (85%)	12 (3%)	41 (10%)	57 (51%)	17 (36%)
High-income countries						
AFRO	0	0	0	0	0	0
AMRO	8	7 (38%)	0	1 (2%)	5 (34%)	2 (4%)
EMRO	6	0	4 (3%)	2 (5%)	0	0
EURO	31	6 (13%)	8 (32%)	16 (26%)	5 (12%)	2 (1%)
SEARO	0	0	0	0	0	0
WPRO	6	3 (2%)	0	3 (10%)	2 (1%)	1 (<1%)
Subtotal	51	16 (40%)	12 (24%)	22 (36%)	12 (36%)	5 (4%)
Total for women	178	88 (76%)	24 (7%)	63 (15%)	69 (48%)	22 (30%)

Data are n, in which n refers to number of countries, or n (%), in which n refers to number of countries and % refers to the proportion of the regional population covered. Table shows data for individuals aged 15 years or older; income categories are from The World Bank. AFRO=WHO African Region. AMRO=WHO Region of the Americas. EMRO=WHO Eastern Mediterranean Region. EURO=WHO European Region. SEARO=WHO Southeast Asian Region. WPRO=WHO Western Pacific Region.

Table 2: **Probability of achieving the target of a 30% relative reduction in tobacco use by WHO region**

Panel: **Research in context**

Systematic review

We searched PubMed with the terms "tobacco" OR "smoking" OR "cigarette" AND "trends" or "projections" for articles published in English before Dec 16, 2014. We identified no articles that provided a comprehensive and comparable systematic assessment of recent trends and projections ensuring consistency for four tobacco use indicators and including target achievement probabilities under the WHO global monitoring framework. We identified articles that estimated recent trends or made projections for a single country or small subsets of countries for one or two indicators.[26–30]

Interpretation

Our findings show that striking between-country disparities in tobacco use would persist in 2025, with many countries not on track towards target achievement and several low-income or middle-income countries at risk of worsening tobacco epidemics if recent trends remain unchanged. Immediate, effective, and sustained action is necessary to attain and maintain desirable trajectories for tobacco control and achieve global convergence towards elimination of tobacco use.

the timeframe of the data, all our projection estimates are subject to the standard limitations of projections based on a functional assumption, irrespective of the sophistication of the Bayesian hierarchical approach. Third, our study did not include estimates for smokeless tobacco, which is an important form of tobacco use. Unfortunately, severe limitations in availability and quality of data for smokeless tobacco compared with smoked forms[43] precluded the inclusion of smokeless tobacco in this study. Additionally, smokeless tobacco could have very different risk factors and use profiles compared with smoked tobacco, and might be better modelled in a separate study focusing on countries known to have appreciable prevalence of this form, rather than as a single indicator in a global study. Fourth, although a formal impact evaluation of the Framework Convention on Tobacco Control has not been done, there is some evidence that it accelerated adoption of some measures for tobacco control,[44] and future shifts occurring after country ratification might not be fully captured in our basis period for projection. However, varying lags in actual implementation of control measures after implementation of the framework, and existing policies for tobacco control in place before the framework, precluded use of the year of ratification as the base point for projections. Instead, we opted to use a common starting point that allowed for a straightforward comparison of projections, and provided a common reference point from which to examine country differences in actual implementation of tobacco control measures. Finally, some of the countries represented in our data had very few datapoints, and the trend estimates for these countries are likely highly affected by regional estimates. For these countries, the trend can be interpreted as their likely future trajectory of tobacco use prevalence if they adopt the tobacco control policies common in their region. Although trend estimates from our research can serve as an indicator of these countries' future tobacco trends, these countries need to improve surveillance and monitoring of tobacco use to properly understand their future risk profile of non-communicable diseases.

Patterns in target achievement probabilities, trajectories, and projected prevalence uncover areas for attention. We estimated low probabilities of target achievement and upward trends in prevalence for most countries in the WHO African region for men and in the WHO eastern Mediterranean region for both sexes. For men, both regions have several countries—six (32%) for the eastern Mediterranean region and 15 (38%) for the African region—with high (≥95%) estimated probabilities of increase, and 37% of the population covered by the African region are almost certain to experience increases in tobacco smoking by 2025 if urgent action is not taken to reverse the progress of the smoking epidemic. Global inequalities in tobacco control continue to exist, with many more high-income than low-income countries achieving reductions in tobacco smoking by 2010, and the future landscape of tobacco control starkly defined by national income: less than 1% of the population of low-income and middle-income countries live in areas with a high probability of achieving tobacco control targets, compared with 36% of the population of high-income countries. International cooperation is thus needed, consistent with evidence that country capacity is a crucial mediator in implementation of tobacco control measures.[45] In view of increasing trends in other risk factors for non-communicable diseases (eg, blood pressure[46] and high body-mass index[47]), and low resources for several countries in these regions, immediate and effective action should be taken to prevent potential epidemics of non-communicable diseases that could burden already-fragile health systems. Tobacco is the most policy-responsive risk factor for non-communicable disesases,[48] and with price the key determinant of initiation and cessation, high specific excise taxes on all brands could prevent increases and induce reductions in prevalence as well as generate revenues for health financing[10] for these countries.

Synthesis of target achievement probabilities and projected prevalence also provides impetus for stronger control strategies for tobacco, even for high-income countries. Projected target achievement should not be taken as cause for complacency; some countries, such as Japan, with greater than 50% probability of achieving the target would still belong to the third-highest quintile of current prevalence of tobacco smoking (29% to <36%) among men in 2025. Our findings lend support to those from a modelling exercise that recommended a more ambitious reduction target for tobacco use to achieve corresponding goals to reduce premature mortality from non-communicable diseases.[48] Although a 30% relative reduction is feasible on the basis of previous experience and is useful for benchmarking progress,[6] it should not hold countries back from aspiring to more challenging yet efficient pathways towards elimination of tobacco use.

Although efforts for tobacco control in the past decade have been successful in reduction of tobacco use in many countries, some countries are at risk of substantial increases in tobacco use, and tobacco control targets remain out of reach for many. If recent trends remain unchanged, we project that many countries will not achieve tobacco control targets and more than 1 billion people will remain current smokers in 2025. Stagnating trends imply that future research is needed to devise ways to accelerate progress and for innovation in tobacco control strategies. Countries in Africa and the eastern Mediterranean, with few resources and fragile health systems, are susceptible to worsening tobacco epidemics, and there is also evidence that the epidemic will persist among women in some high-income countries. Immediate, effective, and sustained action is needed to attain and maintain desirable trajectories towards a tobacco-free world.

Contributors

All authors were involved in study design, data consolidation and processing, model development, analysis, and writing and editing of the report.

Declaration of interests

We declare no competing interests.

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PLOS ONE

RESEARCH ARTICLE

Inequality in Diabetes-Related Hospital Admissions in England by Socioeconomic Deprivation and Ethnicity: Facility-Based Cross-Sectional Analysis

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Abstract

Objective

To investigate the effect of social deprivation and ethnicity on inpatient admissions due to diabetes in England.

Design

Facility-based cross-sectional analysis.

Setting

National Health Service (NHS) trusts in England reporting inpatient admissions with better than 80% data reporting quality from 2010–2011 (355 facilities).

Participants

Non-obstetric patients over 16 years old in all NHS facilities in England. The sample size after exclusions was 5,147,859 all-cause admissions.

Main Outcome Measures

The relative risk of inpatient admissions and readmissions due to diabetes adjusted for confounders.

Results

There were 445,504 diabetes-related hospital admissions in England in 2010, giving a directly (age-sex) standardized rate of 1049.0 per 100,000 population (95% confidence interval (CI): 1046.0–1052.1). The relative risk of inpatient admission in the most deprived quintile was 2.08 times higher than that of the least deprived quintile (95% CI: 2.02–2.14), and the effect of deprivation varied across ethnicities. About 30.1% of patients admitted due to diabetes were readmitted at least once due to diabetes. South Asians showed 2.62 times

(95% CI: 2.51 – 2.74) higher admission risk. Readmission risk increased with IMD among white British but not other ethnicities. South Asians showed slightly lower risk of readmission than white British (0.86, 95% CI: 0.80 – 0.94).

Conclusions

More deprived areas had higher rates of inpatient admissions and readmissions due to diabetes. South Asian British showed higher admission risk and lower readmission risk than white British. However, there was almost no difference by ethnicity in readmission due to diabetes. Higher rates of admission among deprived people may not necessarily reflect higher prevalence, but higher admission rates in south Asian British may be explained by their higher prevalence because their lower readmission risk suggests no inequality in primary care to prevent readmission. Better interventions in poorer areas, are needed to reduce these inequalities.

Introduction

It is well known that socioeconomic deprivation is associated with excess hospital admissions. For example, people in unskilled employment[1], people from a household whose head is in an unskilled-labour social class, or with an adult member of the family who cannot work due to illness, experience higher rates of emergency admission[2]. In the United States, people in highly deprived socioeconomic conditions or from certain ethnic minorities have a higher risk of diabetes-related hospitalization[3]. To the extent that these inequalities in admission rates are preventable, they represent a burden of potentially avoidable hospital admissions which, if addressed, may lead to health service efficiencies.

Diabetes is a typical example of a chronic non-communicable disease. Diabetes patients need continuous careful management in primary care by a general practitioner (GP) to prevent complications that may lead to hospitalization. In Type 1 diabetes, failure of primary care management can lead to acute ketoacidosis, which requires immediate emergency department admission; acute sequelae of untreated or poorly-managed type 2 diabetes can also lead to preventable hospital admissions. In the context of a growing diabetes epidemic in the UK, prevalence of type 1 and type 2 diabetes are expected to increase from approximately 0.6% and 5.4% of the whole population respectively in 2010/2011 to 0.9% and 7.7%, respectively by 2035/2036[4], for assumed population projections at 2035[5]. The annual cost of emergency calls for severe hypoglycaemia is £13.6m for England alone[6], and the total cost of diabetes is estimated to increase from £23.7bn in 2010/2011 to £39.8bn by 2035/2036[4]. Reducing excess inpatient admissions, especially in high-prevalence groups, is important to both reduce unnecessary expenditure on medical services and to reduce demand on NHS hospitals.

In the UK the prevalence of diabetes is estimated to be almost equal across socioeconomic status in men and at most double in women between the highest and lowest social classes[7]. Thus, a socioeconomic gradient in excess hospital admissions due to diabetes in the UK may reflect poorer management of chronic diabetes in this group. Some research also suggests inequality in diabetes primary care by ethnicity[8]. British of black Caribbean or south Asian descent are known to have a higher prevalence of diabetes[9–11] and without good quality management in primary care it is likely that this higher prevalence will be represented in higher rates of emergency admissions.

Excess rates of admission for diabetes represent a health system burden that can be reduced through targeting better quality primary care management of diabetes[12] such as controlling blood glucose concentration and blood pressure[13]. In a period of straitened finances in the UK and significant cuts to both social welfare and health services[14], it is important to understand the role that socioeconomic inequality can play in increasing the burden on health systems, to better prepare for and manage its health system effects. Furthermore, the current agenda for NHS reform in the UK focuses on increasing the role of GPs in clinical commissioning and health service planning[15], suggesting that GPs will be playing a greater future role in public health than has previously been the case, with the risk that flaws in primary care service will have a greater impact on the health system in the future. In this study, we investigate the relationship between socioeconomic deprivation, ethnicity and inpatient admission for diabetes using data for all of England.

Methods

Data sources

Data on individual inpatient hospital admissions was obtained from the inpatient components of the UK Hospital Episode Statistics (HES) data set. This data contains individual records of all attendances occurring in England from 2010–11, and was obtained from the National Health Service (NHS) Information Centre[16]. The population data for Lower Super Output Areas (LSOAs), the key geographical variable on which data on socioeconomic deprivation is available for 2011, was obtained from the website of the Office for National Statistics[17]. This data set contained 8,696,242 all-cause admissions in 498 hospitals.

Patients with obstetric-related diagnostic codes were excluded because gestational diabetes has very different etiology, management and epidemiological patterns than adult diabetes. In the inpatient data, only patients admitted through elective and emergency admission pathways were analyzed and other admission methods (maternity, psychiatric etc.) were excluded.

To avoid duplication of patient data due to follow-up admission, between- or within-facility referral for the same admission period, only the initial admission record for any hospital stay (the first episode of a "spell" in HES terminology) was analyzed This exclusion criterion is standard practice for analysis of admission data in the inpatient dataset[16]. Patients under 16 years old were also excluded from this analysis. Admissions from postcodes in Wales, Scotland, Northern Ireland, the Channel Islands, the Isle of Man, and any "pseudopostcodes" were excluded because these postcodes lack information about the Index of Multiple Deprivation (IMD), and only data for England were analyzed.

Missing data

Before analysis, records were excluded on a facility-wise basis depending on the rate of missing data in key variables. Hospitals with less than 80% valid data on diagnosis were excluded from the data set. Because ethnicity is relatively poorly recorded in the data, analysis of the relationship between hospital admission and ethnicity was restricted to only those hospitals with at least 80% valid data on both diagnosis and ethnicity.

Age-sex standardization of emergency admission rate

Directly standardized inpatient admission rates per 100,000 population were calculated as the age- and sex-standardized mean of the admission rates of each IMD quintile using the whole of England as the reference population. All statistical analysis was conducted on crude admission counts in order to adjust for age and sex.

Covariates

Admission due to diabetes was defined as a hospital admission with primary or secondary diagnosis from the ICD 10 codes E10—E14. IMD was used to express the degree of socioeconomic deprivation. This index is given at the level of small districts called Lower Super Output Areas, each consisting of about 672 households on average[18], and aggregates indices measuring income, employment, health, education, housing services, crime, and the living environment [19]. We adjusted all analyses for the confounding effect of patients' sex, ethnicity, age on the day of admission, and rural-urban indicator. In the HES data, rural-urban indicator is classified into nine categories[20] representing degree of urbanization. For this analysis, we collapsed them into three: urban, town, and village/hamlet. The admission method, elective or emergency, was also adjusted for.

HES data classifies ethnicity into 18 categories[20], but we grouped data into six categories: white, mixed, south Asian, black, Asian, and others.

Statistical analysis

The relationship between regional deprivation and inpatient admission was analyzed using a multiple Poisson regression model with random effects for region (the LSOA) and IMD treated as a region-level variable. Population by broad age groups (16–29, 30–44, 45–64, over 65) at the LSOA level was used as an offset in the regression model. All results from the multiple regression models are presented as relative risks with confidence intervals and p-values. We categorized IMD into quintiles and age into the same broad age groups as were present in the population data. An interaction term between IMD and ethnicity was included in the model to identify effect modification due to ethnicity.

Analysis of high-impact users

Using the same set of inpatient admission data, patients readmitted to hospital for diabetes were identified and their total number of readmissions calculated. To adjust for varying dates of initial admission, the time at risk was calculated in person-years from the first admission to the end of the data collection period (31st March 2011). A small number of patients whose record of observation period exceeded one year were excluded (20,352 patients). After exclusion, 230,535 patients remained. The number of readmissions was analyzed using multi-level Poisson regression. However, a small number of extreme outliers (more than 11 readmissions: 0.05% of the whole dataset) were excluded due to computational problems. The natural log of the person-year was used as the offset in the Poisson regression, and LSOA-level population was excluded because the analysis was only being conducted on the subset of those admitted from each area. Admission method of the initial admission due to diabetes for each patient was included as a covariate in this model, to test the relative risk of readmission of emergency compared to elective patients.

Ethics Considerations

Approval was given for the use of the data by the NHS Information Centre. Because the data is anonymous, routine monitoring data open to the public, further ethics approval is not required.

Results

A flowchart describing the application of exclusion criteria and removal of missing data is summarized in Fig. 1. There were a total of 8,696,242 all-cause admissions in 498 hospitals. After

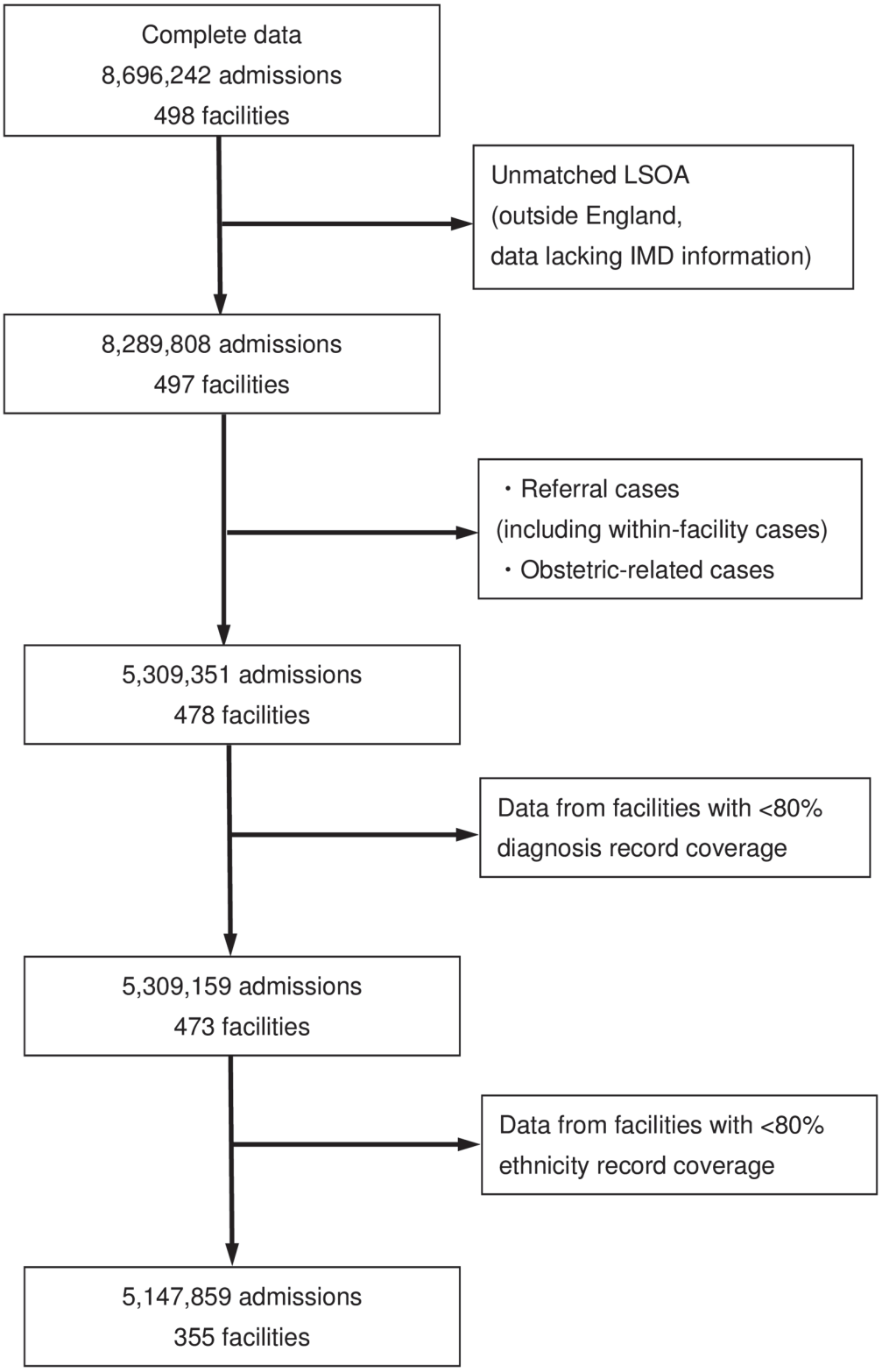

Fig 1. Data exclusion flowchart.

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applying the exclusion criteria, 5,309,351 admissions remained, spread across 478 hospitals. After excluding data with insufficient diagnostic codes and ethnicity data, 5,147,859 records remained in the data set, spread over 355 NHS hospitals. This is 97.0% of all valid attendances and 74.3% of all valid NHS hospitals.

In the whole of England, there were a total of 445,504 diabetes admissions, giving a crude rate of 1049.0 (95% CI: 1046.0–1052.1) admissions per 100,000 population.

Fig. 2 shows IMD quintile-specific directly standardized admission rates. The age-sex standardized admission rate increases with increasing deprivation.

Table 1 shows the result of multiple regression analysis of diabetes admissions by IMD quintile adjusting for ethnicity. Likelihood ratio tests comparing the multi-level model with a simple Poisson regression without random effects in the model showed the random effects were significant. The relative risk of diabetes-related admission increases with IMD quintile. The poorest quintile of white British had a 2.08 times (95% CI 2.02–2.14) higher admission risk than the richest quintile. The risk of diabetes-related admission among south Asian British was 2.62 (95% CI 2.51–2.74) times higher than white British. Although statistically significant, the risk increase among other non-white British was not large. Other risk factors for hospital admission were age, sex and living in an urban area.

The chi square value of the Wald likelihood test of overall interaction terms (185.25, p-value <0.001) shows that there was a statistically significant interaction between ethnicity and deprivation. Fig. 3 shows the relationship between diabetes-related hospital admission risk and IMD quintile, for selected ethnicities calculated from linear combinations of the coefficients shown in Table 1. The effect modifier for south Asian ethnicity showed lower sensitivity to IMD (1.68 times higher risk in the most deprived quintile than the least deprived quintile) than black British (2.28 times higher risk) or white British (2.08 times higher risk). This is suggestive of an attenuated effect of deprivation in south Asian British relative to white and black British.

A total of 174,932 patients were admitted due to diabetes at least once and 73,684 patients were admitted more than once. Table 2 shows the result of Poisson regression of readmission in these patients. For this model the random effect was also significant. The relative risk of diabetes-related readmission also increases with IMD quintile but the association was much weaker than that of admission. The poorest quintile of white British had a 1.18 times (95% CI 1.15–1.22) higher readmission risk than the richest quintile. The relative risk of readmission in south Asian British was 0.86 (95% CI 0.80–0.94) times that of white British. Other ethnic groups did not show significant difference from white British except the "other" ethnic group. Readmission risk was slightly higher in patients whose index admission was elective than those who were admitted through the emergency department. Women showed slightly lower risk of readmission than men. Almost all other covariates showed no significant difference.

Fig. 4 shows the relationship between readmission and IMD by selected ethnicities, calculated from linear combinations of the coefficients shown in the Poisson regression. Black and white British show almost no difference by IMD quintiles, while hospital readmission in more deprived groups was higher in white British though the relationship is attenuated.

Discussion

This is the first study to analyze the effect of socioeconomic deprivation and ethnicity on inpatient hospital admission and readmission due to diabetes using inpatient admission data for all of England, by deprivation quintiles and by ethnic groups. Our study is the first analysis of HES data for the whole of England to use multi-level modeling in the statistical analysis. We used IMD as a second level effect, because IMD is calculated at the level of LSOA rather than

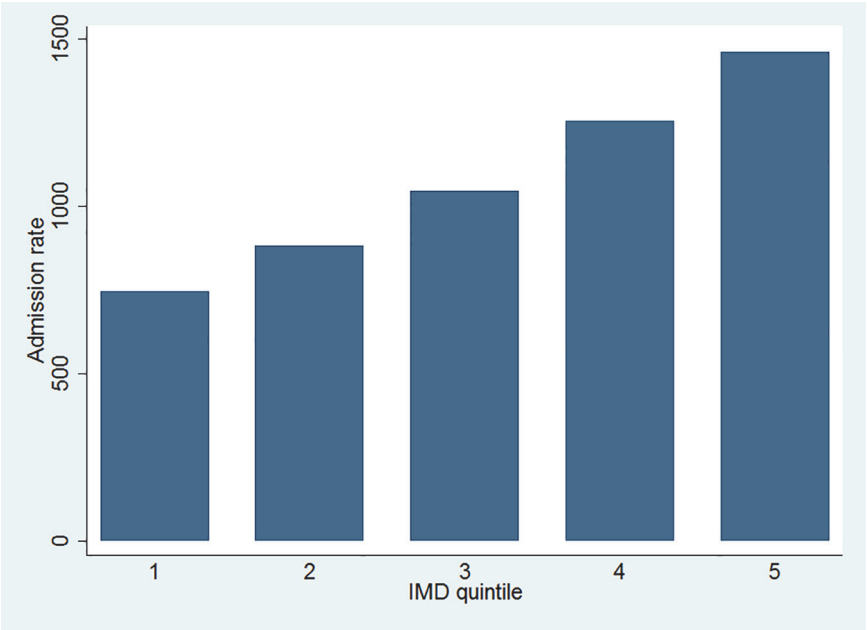

Fig 2. IMD quintile-specific directly standardized admission rate due to diabetes.

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for individuals[19]. This enables our study to incorporate the effect of unmeasured community-level influences on hospital admission risk.

In this study we found that risk of inpatient admission for diabetes increases with increasing socioeconomic deprivation measured by IMD quintile, and that although the relationship exists across all ethnicities it is strongest in white and black British. The relative risk of hospital admission in the most deprived quintile among white British was 2.08 (95% CI 2.02–2.14) times higher than the least deprived quintile. The relative risk in the most deprived quintile was 1.68 (95% CI: 1.58–1.77) times and 2.28 (95% CI: 2.02–2.57) times higher than the least deprived quintile among south Asian and black British, respectively. Admission risk was 1.61 times (95% CI: 1.60–1.62) higher for transfer from emergency departments than through elective or planned admission pathways.

This research also found that ethnic minority groups are at higher risk of hospital admission for diabetes compared to white British people even after adjusting for socioeconomic deprivation. For diabetes, this may reflect the known differences in prevalence between South Asian, white and black British[9–11]. We found readmission rates in most non-white groups were not significantly different from the white group, though the smaller number of observations gave wider confidence intervals. This suggests that the relationship between ethnicity and inpatient admission may reflect racially-specific higher prevalence, but may also be a function of differences in primary care management or health-seeking behavior[21]. By contrast, this study found that people from poorer areas had higher rates of readmission, even after adjusting for ethnicity. Even though they were admitted once, after discharge the same people in these socioeconomic groups were more likely to be admitted to hospital again. This suggests that prevalence alone does not account for the differences in admission risk by IMD.

The two main possible causes of the increased risk of hospital admissions and readmissions in poorer areas are excess prevalence of individual risk factors in poorer individuals, or poorer management of diabetes in primary care in poorer areas[22]. One of the most important risk factors for diabetes is obesity, and the prevalence of obesity is inversely associated with

Table 1. Multiple regression model of relationship between hospital admission due to diabetes, IMD quintile and ethnicity.

Variables	Relative Risk	95% Confidence Interval	P-value
IMD quintile			
Quintile 1 (Least Deprived)	1	N.A.	
Quintile 2	1.16	1.13–1.19	<0.001
Quintile 3	1.35	1.32–1.39	<0.001
Quintile 4	1.68	1.63–1.73	<0.001
Quintile 5 (Most Deprived)	2.08	2.02–2.14	<0.001
Age			
16–29 years	1	N.A.	
30–44 years	2.28	2.22–2.34	<0.001
45–64 years	5.88	5.74–6.02	<0.001
65 + years	14.17	13.83–14.51	<0.001
Sex			
Men	1	N.A.	
Women	0.64	0.63–0.64	<0.001
Region type			
Urban	1	N.A.	
Town	0.89	0.87–0.91	<0.001
Village	0.81	0.80–0.83	<0.001
Ethnicity			
White	1	N.A.	
Mixed	1.49	1.29–1.72	<0.001
South Asian	2.62	2.51–2.74	<0.001
Black	1.22	1.09–1.37	0.001
Asian	1.02	0.87–1.21	0.783
Others	1.32	1.21–1.43	<0.001
IMD/ethnicity interaction			
IMD Quintile 1: all	1	N.A.	
IMD Quintile 2:			
Mixed	0.83	0.68–1.01	0.061
South Asian	0.91	0.86–0.97	0.004
Black	1.23	1.07–1.42	0.004
Asian	1.22	0.95–1.57	0.111
Others	1.03	0.92–1.16	0.585
IMD Quintile 3:			
Mixed	1.15	0.97–1.37	0.10
South Asian	0.85	0.81–0.91	<0.001
Black	1.20	1.05–1.36	0.006
Asian	0.83	0.65–1.06	0.135
Others	1	0.90–1.11	0.946
IMD Quintile 4:			
Mixed	0.73	0.61–0.86	<0.001
South Asian	0.81	0.77–0.86	<0.001
Black	1.12	0.99–1.26	0.068
Asian	1.10	0.89–1.36	0.371
Others	0.89	0.80–0.98	0.019

(*Continued*)

Table 1. (*Continued*)

Variables	Relative Risk	95% Confidence Interval	P-value
IMD Quintile 5:			
Mixed	0.86	0.73–1.01	0.074
South Asian	0.81	0.77–0.85	<0.001
Black	1.10	0.97–1.24	0.127
Asian	1.07	0.87–1.32	0.538
Others	0.86	0.78–0.95	0.003
Admission method			
Elective	1	N.A.	
Emergency	1.61	1.60–1.62	<0.001
Likelihood ratio statistic against without random effect mode (p-value)		129728.94(<0.001)	

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socioeconomic status in developed nations[23]. Type 2 diabetes prevalence increased in the UK between 1994 and 2006 and the increase was associated with socioeconomic inequality measured by social class categories[7], though there was no consistent pattern in individual risk factors[24].

In the UK, the poor and ethnic minorities are more likely to consult their GP than secondary care[25] and people from more deprived socioeconomic backgrounds use all forms of medical services less frequently[8]. Although historical socioeconomic disparities in diabetes care [26] seem to have reduced[24], it has been suggested that there is still poorer control of risk factors such as HbA_{1c} in more deprived white British[27]. In the context of the pathway of care through Britain's health system, this result suggests a failure of the primary care gate-keeping role, leading to increased need for secondary care for diabetic patients in highly deprived areas. In the most deprived areas and the areas with the worst health and deprivation indicators (so-

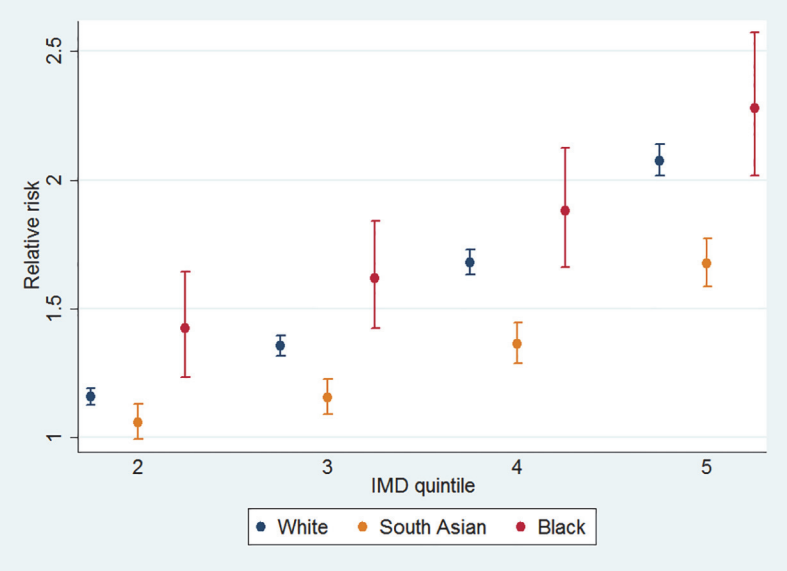

Fig 3. Sensitivity of relative risk of admission to IMD quintiles by ethnicity.

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Table 2. Multiple regression model of relationship between number of hospital readmissions due to diabetes, IMD quintile and ethnicity.

Variables	Relative Risk	95% Confidence Interval	P-value
IMD quintile			
Quintile 1 (Least Deprived)	1	N.A.	
Quintile 2	1.02	0.99–1.05	0.166
Quintile 3	1.06	1.03–1.10	<0.001
Quintile 4	1.13	1.09–1.16	<0.001
Quintile 5 (Most Deprived)	1.18	1.15–1.22	<0.001
Age			
16–29 years	1	N.A.	
30–44 years	0.91	0.87–0.96	<0.001
45–64 years	0.97	0.93–1.01	0.128
65 + years	1.02	0.97–1.06	0.453
Sex			
Men	1	N.A.	
Women	0.90	0.89–0.91	<0.001
Region type			
Urban	1	N.A.	
Town	1.03	1.00–1.06	0.079
Village	1.01	0.98–1.03	0.723
Ethnicity			
White	1	N.A.	
Mixed	1.01	0.79–1.29	0.964
South Asian	0.86	0.80–0.94	0.001
Black	1.03	0.84–1.26	0.779
Asian	0.73	0.53–1.01	0.058
Others	1.16	1.02–1.33	0.026
IMD ethnicity interaction			
IMD Quintile 1: all	1	N.A.	
IMD Quintile 2:			
Mixed	1	0.71–1.39	0.981
South Asian	1.06	0.95–1.19	0.270
Black	1.11	0.87–1.42	0.383
Asian	0.96	0.59–1.57	0.111
Others	0.77	0.63–0.93	0.007
IMD Quintile 3:			
Mixed	1.17	0.86–1.58	0.313
South Asian	1.04	0.94–1.14	0.499
Black	0.92	0.73–1.14	0.432
Asian	0.80	0.49–1.32	0.387
Others	0.77	0.65–0.92	0.003
IMD Quintile 4:			
Mixed	0.92	0.69–1.23	0.582
South Asian	1.03	0.94–1.14	0.495
Black	0.92	0.74–1.13	0.411
Asian	1.29	0.85–1.95	0.230
Others	0.91	0.78–1.07	0.264

(*Continued*)

Table 2. (*Continued*)

Variables	Relative Risk	95% Confidence Interval	P-value
IMD Quintile 5:			
Mixed	0.78	0.58–1.04	0.092
South Asian	0.97	0.88–1.07	0.543
Black	0.92	0.74–1.13	0.404
Asian	1.80	1.22–2.65	0.003
Others	0.82	0.70–0.96	0.014
Admission method			
Elective	1	N.A.	
Emergency	0.85	0.84–0.86	<0.001
Likelihood ratio statistic against without random effect model (p-value)		9465.53 (<0.001)	

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called Spearhead areas), GPs obtain lower scores on the quality and outcomes framework (QOF), an indicator of quality of primary care. Practices in Spearhead areas have lower numbers of GPs per practice and higher caseloads for each GP, which may lead to lower quality of practice[28]. Poorer management of diabetes and higher prevalence of undiagnosed diabetes, combined with restricted access to medical services and poorer patterns of health-seeking behavior, is likely to lead to an increased burden on secondary care services, and our results confirm this increased service use.

Higher rates of admission we observed in some ethnicities may also be partially explained by higher prevalence. In a recent study, the age-standardized prevalence of diabetes in black British and south Asian descendants was two or three times that of white British, respectively [29]. The higher risk of inpatient admission is consistent with this difference in prevalence. There is some evidence that black and south Asian British are treated with HbA_{1c} control more intensively[30], although findings about quality of primary care in ethnic minorities are

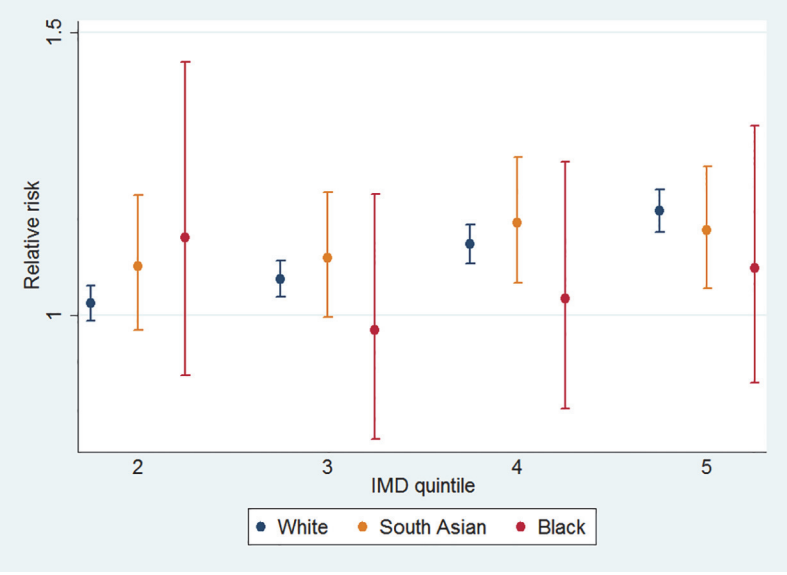

Fig 4. Sensitivity of relative risk of readmission to IMD by ethnicity.

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inconsistent[8,31]. We could not adjust for body mass index (BMI) in this analysis due to unavailability of this data in the HES data, and the high rates of admission in some ethnicities may be partly explained by racial differences in the role of this risk factor. A Canadian study has shown that south Asian and black people can develop diabetes at lower BMI thresholds than white people, though the mechanism is not understood[32]. Recent NICE guidance on assessing BMI thresholds finds that south Asian and black people may have equivalent risk in lower BMI than white people, but the guidance does not specify ethnicity-specific thresholds due to insufficient evidence[33]. The result of our study suggests that primary care in these ethnic minorities may not be sufficiently managed, though the guidance recommends multi-component interventions in ethnic minorities[33]. On the other hand, in light of this potential differential risk structure, the finding of almost no difference in readmission rates among non-white ethnicities and slightly lower risk of readmission in south Asians may mean this more intensive care in these ethnic groups may have improved diabetic condition and reduced the risk of readmission. Considering these results, first diagnosis of diabetes may be a key to address the inequality in risk of admissions. A better understanding of both prevalence and readmission pathways is necessary in these ethnicities to better understand the causes of the inequalities observed in this study.

Because this study uses a secondary data collection, it is subject to several limitations. We could not adjust for any individual confounding factors beyond age and sex, so could not adjust for the confounding effect of health background including severity of disease, occupation, employment status, educational history or whether patients have already received medical care against diabetes before hospital admission. Future research using data linking hospital admissions and primary care databases should focus on the pathway from primary to secondary care, to identify possible causes of the increased risk of diabetes-related admission in more socioeconomically deprived areas.

This study has found a strong association between socioeconomic deprivation and ethnicity and diabetes-related inpatient admission. Action needs to be urgently taken to reduce preventable hospital admissions by:

- Increasing attention on the quality of management of NCDs and their risk factors in primary care, especially in "Spearhead" areas with large deprived populations. Current attempts to improve primary care management of diabetes are focused on the quality and outcomes framework (QOF) but there is limited evidence that this is working effectively in "Spearhead" areas. Furthermore, south Asian and Black patients are more likely to be excluded from QOF measures, and these excluded patients are less likely to achieve intermediate treatment targets[34]. To avoid such problems, the incentive structure built into this program needs to be changed to better reflect the growing NCD epidemic
- Increasing community awareness of diabetes and promoting healthy behavior through mass media or education emphasizing the importance of early diagnosis, better dietary and blood-sugar monitoring amongst those already diagnosed, and more regular primary care visits. These screening, prevention and management efforts should be especially focused in highly deprived areas
- Development of innovative methods to target deprived areas and high-risk ethnic groups for improvements in diabetes treatment and management. This will include improvements in community nursing and continuity of care; development of care plans implementable in primary care and easily understood by patients; inclusion in care plans of targets to reduce inpatient admissions; and improvements in timeliness of access to outpatient care. These

methods will need to use the new coordination and funding powers of the clinical commissioning groups (CCGs) that were established in April 2013[35].

- Constructing a nationally standardized referral database which can be shared by all NHS facilities, CCGs and GPs to understand and improve referral patterns. This will require renewed commitment to information systems reform, which will be challenging given resource constraints and the limited progress of the NHS Care Records Service[36].

The UK diabetes research agenda needs to consider ways to improve research on the relationship between diabetes prevalence and socioeconomic deprivation and ethnicity. Better, more accurate measures of prevalence of diabetes are essential in order to better understand the extent of the problem in England, and to enable measures of hospital admission intensity to be standardized by disease prevalence rather than total population. These measures can be achieved by expanding the coverage and scope of the Health Survey for England, over-sampling areas with high ethnicities and deprived areas, and increasing the detail and scope of the NCD sections of this survey, and also by using the central coordinating authority of the Information Centre to identify local and regional datasets that may contain important information on regional and local variations in prevalence. Improvements in collection of ethnicity and diagnostic codes in the hospital episode statistics data are also essential.

Inequality in health outcomes as a result of NCDs is not inevitable and can be reversed. For example, IMD has no influence on survival due to heart failure and numbers of patients with a first hospital admission with heart failure reached a plateau in 1998[37]. This suggests that medical care for heart failure has been improved for people from all socioeconomic backgrounds, but for diabetes is still insufficient. Through better attention to primary care management of diabetes, at least some part of the inequity in health outcomes experienced by the most deprived members of British society can be reduced.

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Author Contributions

Analyzed the data: YN SG KS. Wrote the paper: YN SG KS.

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Catastrophic household expenditure on health in Nepal: a cross-sectional survey

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Objective To determine the incidence of – and illnesses commonly associated with – catastrophic household expenditure on health in Nepal.
Methods We did a cross-sectional population-based survey in five municipalities of Kathmandu Valley between November 2011 and January 2012. For each household surveyed, out-of-pocket spending on health in the previous 30 days that exceeded 10% of the household's total expenditure over the same period was considered to be catastrophic. We estimated the incidence and intensity of catastrophic health expenditure. We identified the illnesses most commonly associated with such expenditure using a Poisson regression model and assessed the distribution of expenditure by economic quintile of households using the concentration index.
Findings Overall, 284 of the 1997 households studied in Kathmandu, i.e. 13.8% after adjustment by sampling weight, reported catastrophic health expenditure in the 30 days before the survey. After adjusting for confounders, this expenditure was found to be associated with injuries, particularly those resulting from road traffic accidents. Catastrophic expenditure by households in the poorest quintile were associated with at least one episode of diabetes, asthma or heart disease.
Conclusion In an urban area of Nepal, catastrophic household expenditure on health was mostly associated with injuries and noncommunicable diseases such as diabetes and asthma. Throughout Nepal, interventions for the control and management of noncommunicable diseases and the prevention of road traffic accidents should be promoted. A phased introduction of health insurance should also reduce the incidence of catastrophic household expenditure.

Abstracts in عربي, 中文, Français, Русский and Español at the end of each article.

Introduction

In many developing countries, a large proportion of the money spent on health care comes from the out-of-pocket expenditure of patients or their families. In Bangladesh, India and Nepal, for example, this proportion has been estimated to be 48–69%.[1] Households in such countries can experience financial hardship and often impoverishment as a result of their spending on health care.[2–5] In the long term, financial protection against the risk of catastrophic health expenditure at household level can be achieved through tax-based health financing systems or social health insurance schemes – or a combination of both.[6] In developing countries that have inadequate public funds for health, some transitional measures such as voluntary community-based health insurance schemes may be introduced.[7] Low-income countries are increasingly either implementing essential health packages for disease treatment free of charge or providing patients – or their families – with conditional cash transfers for selected health services. Such interventions may often use up a large share of a country's public health subsidies.[8]

Nepal is a low-income country. In 2011its gross domestic product was 620 United States dollars (US$) per capita.[9] Since 2006, certain health care services – including the drugs on a national essential drugs list – have been available free of charge at publicly funded district hospitals, health posts, sub-health posts and primary health-care centres.[10] A Safe Delivery Incentive Programme was implemented throughout Nepal in 2005. This programme has provided pregnant women with cash incentives to encourage institutional delivery and, since 2009, it has also made deliveries free of charge at government facilities and some private facilities.[11] The Nepalese government subsidizes the treatment of cancers, heart disease, kidney disease and other severe diseases up to a maximum of 50 000 Nepali rupees per patient – just over US$ 500 at the mean exchange rate for 2014.[10] Although voluntary community-based health insurance schemes are being piloted in six districts of Nepal, their coverage remains sporadic and there is no other publicly-run health insurance scheme in the country.[10]

Despite the treatment subsidies and pilot insurance schemes in Nepal, the incidence and main causes of catastrophic household expenditure on health have not been investigated in detail in the country. It remains unclear if the existing public subsidies that target specific diseases are providing reasonable financial protection to the general population. There have only been a few attempts to determine the effect of disease-specific medical costs on household economic status in southern Asia[5,12,13] or to determine which illnesses have the most impact on household expenditure.[14–17] We therefore estimated the incidence of – and determined the illnesses that were most commonly associated with – catastrophic household expenditure on health in an urban area of Nepal.

Methods

Study design

We used a multivariate Poisson regression model to analyse self-reported data – on illness and financial expenditure in the previous 30 days – that we collected in a population-based

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cross-sectional household survey in Kathmandu Valley. The survey covered all five municipalities in Kathmandu Valley: Bhaktapur, Kathmandu, Kirtipur, Lalitpur and Madhyapur-Thimi. We used data from the 2011 national census as the sampling frame and the corresponding census enumeration areas as the primary sampling units. We aimed to sample a total of 2000 households – by multi-stage cluster sampling – between November 2011 and January 2012. We based our choice of sample size on a cluster sampling method, the precision of the estimates required for the study[18] and an estimate of the prevalence of hypertension in the study area (8%) – assuming that hypertension in those over 20 years of age may represent a major economic burden within the study households.[19] For the first stage of the sampling, 100 enumeration areas were selected, using systematic sampling with probability proportional to the number of households in each area. For the second stage, a cluster of 20 dwellings was selected in each selected enumeration area. If a selected dwelling contained more than one household, one household in that dwelling was randomly selected. We considered an eligible respondent to be the household head or the most knowledgeable adult in a selected household. To collect data, we used a standardized questionnaire – pre-tested in 100 households in the city of Lalitpur – that included questions on household demographics, education, expenditure and durable goods, self-reported episodes of disease, care-seeking behaviour, total health-related expenditures and inpatient health expenditures, and the coping strategies that household members followed to finance health care (Appendix A; available at http://www.ghp.m.u-tokyo.ac.jp/wp-content/uploads/2014/07/Appendix-A.pdf).

We recorded morbidities that had reportedly occurred in the 30 days before the survey and any chronic conditions that had reportedly continued for more than 3 months in the 12 months before the survey. Each reported illness that had been diagnosed by an allopathic or ayurvedic doctor and the symptoms of any undiagnosed illness were coded according to a disease list that we based on the results of previous studies[12,20] and a focus group discussion conducted with health workers in Kathmandu (Appendix A). Whenever possible, interviewers cross-validated a reported diagnosis with the corresponding outpatient card or hospital discharge report. To assess the differences of disease occurrence across economic quintiles we conducted χ^2 tests.

Expenditure

The out-of-pocket expenditure on health of each study household – over the 30 days before the survey – was estimated by asking the respondents how much their households had spent, separately, on consultation or diagnosis fees, drugs, other medical supplies and hospitalization costs. The interviewers also posed separate questions on the costs of traditional healers, homeopathic treatments, ayurvedic treatments and home remedies. We also asked each respondent to give a single aggregated estimate of their household's total expenditure on health in the previous 30 days to see if – as in previous studies[21,22] – this estimate fell substantially below the sum of the respondent's corresponding separate estimates of expenditure on several aspects of health care – i.e. the disaggregated estimate. We used Wilcoxon rank sum test to compare the respondents' aggregated and disaggregated estimates. Total household expenditure was estimated from the reported consumption, in the 30 days before the survey, of purchased and home-produced goods, including foods, non-foods, housing and durable goods. This estimated expenditure and an adult-equivalent score – based on the number and ages of the members of the household – for each household were then used to identify the economic quintile to which each study household belonged.[23] Quintiles 1 and 5 represented the poorest and wealthiest households, respectively.

Comorbidity costs

Some of our study subjects had experienced concurrent episodes of two or more illnesses that were treated concurrently. Such subjects were generally only able to report the total costs of health care for the comorbidities. In these circumstances, we used a regression-based approach – similar to that used by Trogdon et al.[24] – to allocate a proportion of the jointly reported costs to each illness. More details of such cost allocation are available in Appendix A.

Catastrophic health expenditure

If, in the 30 days before the survey, a study household had spent more than 10% of its total expenditure on health care, that household was considered to have experienced catastrophic health expenditure in that period.[2,4] For the study households in general and for each economic quintile of the study households, we assessed the impact on household economic welfare of out-of-pocket spending on each of the 10 types of illness that were most commonly reported. We used the concentration index[25] to see if the percentage of households that experienced catastrophic health expenditure was unequally distributed across the five economic quintiles. Concentration indexes with 95% confidence intervals (CI) and their associated *P*-values were calculated using bootstrapping with 100 iterations and the delta method.[26–28] The concentration index can range between −1 and +1. In our study, indexes well below and well above zero would indicate that catastrophic expenditure is concentrated among the relatively poor and relatively wealthy households, respectively. We measured the intensity of expenditure burden using catastrophic overshoot, i.e. the average of payments surpassing the catastrophic threshold across all households, expressed as the proportion of additional payments above 10% of the total household consumption and averaged by the total number of households. A concentration index significantly below zero indicates a greater overshoot among the poor. We also report the mean positive overshoot, i.e. the share of additional payments above 10% of the total household consumption, averaged by the number of households with catastrophic expenditure.

Analysis of risk factors

We used a Poisson regression model to predict the incidence of catastrophic health expenditure among households affected by a particular illness. We stratified the model by household economic quintile to assess the relative risk – of catastrophic household expenditure – posed by each of the commonly reported illnesses in each quintile. The variables included in the model were: whether there was a history of hospitalization in the previous 30 days; the number of people in the household; whether the household had used a health-care provider in the previous 30 days and, if so, whether the provider or providers used by the household in the previous 30 days were public, private or both public

and private; the age of the household head; whether the household head had primary or lower, secondary or higher education; the number of children aged less than five years in the household; the number of people aged over 65 years in the household; and whether, in the previous 30 days, a household member had reportedly suffered more than one episode of the 10 most commonly reported illnesses. We adjusted all analyses for the sampling structure of the survey. The results are reported as rate ratio (RR) and 95% CI. All the analyses were performed using Stata version 12.1 (StataCorp. LP, College Station, United States of America).

Ethical approval

Ethical approval was given by the Ethics Committee of the University of Tokyo and – under registration number 49/2011 – by the Nepal Health Research Council. Written informed consent was obtained from the participating respondents before they were interviewed.

Table 1. **Characteristics of the study households, Nepal, 2011–2012**

Household characteristic	Value[a]
Mean no. of household members (95% CI)	4.4 (4.3 to 4.5)
Proportion of household members (95% CI) (*n* = 9177)	
Aged < 5 years	0.09 (0.07 to 0.10)
Aged > 65 years	0.05 (0.04 to 0.06)
Mean age of household head, years (95% CI) (*n* = 1997)	46.1 (44.7 to 47.5)
No. (%) of household heads (*n* = 1997)	
Male	1653 (84.2)
Female	344 (15.9)
With no education	532 (24.0)
Educated only to primary level	259 (13.4)
Educated only to secondary level	575 (31.6)
With higher education	631 (31.0)
Owning home	1148 (46.0)
Renting	794 (50.0)
In home provided free of charge	14 (0.6)
Squatting/occupying land illegally	40 (3.4)
Living in other types of dwelling	1 (0.1)

CI: confidence interval.
[a] Adjusted for sample weights.

Results

Morbidity, provider choices and costs

Some details of the study households are shown in Table 1. As no consenting respondents could be found in three households, data were collected from 1997 (99.8%) of the 2000 selected households. The 10 illnesses that were most commonly reported as occurring among members of the study households – in the 30 days before interview – are shown in Table 2. Cases of common cold and concurrent cough and fever were grouped as cold/cough/fever, since many household members reportedly suffered these complaints simultaneously. Hypertension among household members aged more than 20 years appeared to be positively correlated with household expenditure (Table 2). In the 30 days before interview, members of the study households who needed health care had mostly used just private providers or a combination of private providers with other types of facilities (Appendix A). When comparing the respondents' aggregated and disaggregated estimates of their households' out-of-pocket spending on health using a nonparametric test, we found little difference between the two types of estimate ($z = 0.102$, $P = 0.92$).The disaggregated estimates

Table 2. **Illnesses most commonly reported as occurring in the previous 30 days, by economic quintile,[a] Nepal, 2011–2012**

Illness	% of households (95% CI)						Difference between groups, *P*[b]
	All (*n* = 1997)	Quintile 1 (*n* = 371)	Quintile 2 (*n* = 359)	Quintile 3 (*n* = 401)	Quintile 4 (*n* = 415)	Quintile 5 (*n* = 451)	
All household members							
Cold/cough/fever	12.8 (11.2 to 14.4)	12.9 (10.1 to 15.7)	11.6 (9.4 to 13.8)	13.7 (10.3 to 17.0)	13.2 (9.9 to 16.4)	12.6 (10.5 to 14.8)	0.811
Gastritis/peptic ulcer	3.6 (2.8 to 4.3)	5.5 (3.3 to 7.6)	2.8 (1.8 to 3.7)	3.8 (2.4 to 5.2)	3.4 (2.3 to 4.5)	2.4 (1.5 to 3.2)	0.008
Arthritis	2.9 (2.3 to 3.5)	2.4 (1.6 to 3.2)	4.8 (3.1 to –6.6)	2.7 (1.9 to 3.5)	2.2 (1.4 to 3.0)	2.1 (1.3 to 3.0)	< 0.001
Asthma	1.1 (0.9 to 1.4)	1.3 (0.6 to 2.0)	0.9 (0.3 to 1.5)	1.0 (0.5 to 1.4)	1.5 (0.8 to 2.1)	1.0 (0.6 to 1.5)	0.526
Migraine/headache	0.9 (0.6 to 1.2)	1.3 (0.5 to 2.1)	0.5 (0.2 to 0.8)	1.2 (0.4 to 2.0)	0.9 (0.1 to 2.6)	0.6 (0.2 to 1.1)	0.336
Injury	0.7 (0.5 to 1.0)	1.1 (0.5 to 1.7)	0.4 (0.0 to 0.8)	0.6 (0.2 to 1.0)	0.7 (0.3 to 1.0)	1.0 (0.4 to 1.7)	0.202
Heart disease	0.6 (0.4 to 0.8)	0.8 (0.3 to 1.2)	0.3 (0.1 to 0.6)	0.6 (0.2 to 1.0)	0.5 (0.1 to 0.8)	1.0 (0.5 to 1.4)	0.132
Household members aged > 20 years							
Diabetes	3.7 (3.1 to 4.3)	2.3 (1.0 to 3.6)	3.1 (1.7 to 4.5)	3.8 (2.7 to 4.8)	3.8 (2.6 to 5.1)	5.3 (3.8 to 6.8)	0.045
Hypertension	10.5 (9.2 to 11.7)	5.8 (3.9 to 7.8)	9.4 (7.0 to 11.9)	11.9 (9.4 to 14.3)	11.4 (9.1 to 13.7)	13.4 (10.9 to 15.9)	< 0.001
Hyperuricaemia	0.7 (0.3 to 1.1)	0.3 (0.0 to 0.5)	1.6 (0.2 to 3.1)	1.1 (0.0 to 2.3)	1.3 (0.3 to 2.3)	1.0 (0.2 to 1.9)	0.291

CI: confidence interval.
[a] Quintile 1 represents the poorest households and quintile 5 represents the wealthiest households.
[b] Calculated using χ^2 tests.

Table 3. **Household out-of-pocket spending on health care in the previous 30 days, by economic quintile,[a] Nepal, 2011–2012**

Expenditure	Households that reported expenditure on health					
	All (*n* = 1 517)	Quintile 1 (*n* = 270)	Quintile 2 (*n* = 275)	Quintile 3 (*n* = 301)	Quintile 4 (*n* = 324)	Quintile 5 (*n* = 347)
Costs per household, Nepalese rupees (SE)[b]						
Outpatient	1 999 (202)	1 564 (266)	2 123 (664)	1 559 (149)	2 037 (242)	2 722 (514)
Inpatient	39 657 (6 310)	25 200 (12 437)	51 147 (20 377)	26 059 (8 153)	34 578 (7 170)	50 044 (8 104)
Ayurvedic	861 (138)	301 (55)	907 (251)	828 (131)	759 (460)	1 268 (340)
Other traditional medicine or healers	335 (100)	263 (117)	239 (80)	346 (130)	512 (336)	319 (117)
Transportation and other costs	471 (74)	31 (8)	143 (53)	98 (28)	90 (36)	69 (26)
Proportion of total household expenditure represented by out-of-pocket spending on health care, % (SE)	10.1 (1.26)	10.7 (1.55)	14.8 (3.80)	8.3 (1.81)	10.3 (3.24)	6.9 (1.48)

SE: standard error; US$: United States dollars.
[a] Quintile 1 represents the poorest households and quintile 5 represents the wealthiest households.
[b] The average conversion rate during the study was 1 Nepalese rupee to US$ 0.012.

indicated that households in the richest economic quintile spent a considerably smaller share of their total expenditure on health (6.9%) than the other households (range: 8.3% in quintile 3 to 14.8% in quintile 2; Table 3).

Catastrophic health spending

Incidence and intensity

According to the respondents, 13.8% of the study households had experienced catastrophic expenditure on health in the 30 days before interview (Table 4). Such expenditure was most frequently associated with episodes of hypertension, followed – in descending order of frequency – by cold/cough/fever, diabetes and asthma (Table 4). Catastrophic expenditure associated with certain illnesses – such as migraine/headache (concentration index: −0.879; $P < 0.001$) – appeared to be concentrated among the relatively poor households. When we investigated the level by which out-of-pocket treatment costs for each of the commonly reported illnesses exceeded the threshold for catastrophic expenditure, we found that the treatment costs for cold/cough/fever (concentration index: −0.392; $P < 0.001$) and migraine/headache (concentration index: −0.901; $P < 0.001$) appeared to exceed those that the poorer households could bear (Table 5).

Determinants

The risk of catastrophic spending on health – in the 30 days before interview –

Table 4. **Distribution of catastrophic health expenditure in previous 30 days, divided by major illness, Nepal, 2011–2012**

Illness	Catastrophic expenditure		Catastrophic overshoot[a]		Mean positive overshoot (%)[b]
	% of study households (*n* = 1997)[c]	Concentration index (95% CI)	%[c]	Concentration index (95% CI)	
Any	13.8	−0.126 (−0.184 to −0.069)	4.6	−0.045 (−0.195 to 0.105)	33.2
Hypertension	1.3	−0.206 (−0.417 to 0.004)	0.1	−0.224 (−0.462 to 0.116)	10.7
Cold/cough/fever	1.2	−0.262 (−0.459 to −0.066)	0.1	−0.392 (−0.539 to −0.245)	6.8
Diabetes	1.1	−0.099 (−0.304 to 0.107)	0.1	−0.250 (−0.617 to 0.118)	10.2
Asthma	1.0	−0.185 (−0.389 to 0.018)	0.1	0.008 (−0.536 to 0.552)	12.3
Gastritis/peptic ulcer	0.9	−0.111 (−0.447 to 0.225)	0.2	0.364 (−0.111 to 0.839)	17.9
Injury	0.8	−0.033 (−0.328 to 0.261)	0.4	0.011 (−0.479 to 0.501)	49.3
Arthritis	0.7	−0.233 (−0.467 to 0.014)	0.3	−0.395 (−0.830 to 0.041)	41.2
Heart disease	0.5	−0.247 (−0.497 to 0.002)	0.0	−0.194 (−0.511 to 0.122)	8.3
Migraine/headache	0.2	−0.879 (−0.957 to −0.801)	0.0	−0.901 (−0.981 to −0.821)	4.8
Hyperuricaemia	0.2	0.426 (0.379 to 0.473)	0.0	0.426 (0.379 to 0.473)	5.0

CI: confidence interval.
[a] The mean value by which household out-of-pocket expenditure on the illness – as a percentage of total household expenditure – exceeded the 10% threshold used to define catastrophic household expenditure.
[b] The mean level by which out-of-pocket expenditure on the illness, by a household reporting catastrophic health expenditure, exceeded the 10% threshold used to define catastrophic household expenditure.
[c] Adjusted for sampling weight.

Table 5. **Illness and the risk of catastrophic health expenditure in the previous 30 days, by economic quintile,[a] Nepal, 2011–2012**

Illness[b]	Rate ratio (95% CI)				
	Quintile 1	Quintile 2	Quintile 3	Quintile 4	Quintile 5
Diabetes	2.37 (1.16 to 4.83)	2.13 (1.03 to 4.41)	2.85 (1.67 to 4.84)	1.14 (0.61 to 2.13)	1.04 (0.45 to 2.39)
Heart disease	2.24 (1.29 to 3.88)	0.76 (0.26 to 2.27)	1.19 (0.50 to 2.85)	2.17 (0.74 to 6.43)	2.36 (0.83 to 6.71)
Asthma	2.09 (1.28 to 3.42)	1.62 (0.73 to 3.59)	1.94 (1.12 to 3.36)	4.26 (1.89 to 9.61)	1.39 (0.40 to 4.82)
Arthritis	1.72 (0.82 to 3.63)	2.21 (1.24 to 3.94)	1.29 (0.67 to 2.48)	2.32 (1.14 to 4.70)	1.91 (0.75 to 4.88)
Hypertension	1.66 (0.87 to 3.15)	3.26 (1.21 to 8.81)	1.47 (0.81 to 2.67)	1.52 (0.92 to 2.51)	1.62 (0.69 to 3.81)
Migraine/headache	1.64 (0.74 to 3.68)	4.35 (1.71 to 11.04)	1.96 (0.58 to 6.60)	2.29 (0.93 to 5.62)	NA[c]
Gastritis	1.55 (0.76 to 3.17)	1.29 (0.63 to 2.66)	1.32 (0.73 to 2.38)	1.45 (0.77 to 2.74)	2.09 (0.86 to 5.06)
Cold/cough/fever	1.25 (0.57 to 2.73)	2.20 (1.10 to 4.40)	0.85 (0.47 to 1.52)	0.91 (0.43 to 1.94)	0.87 (0.40 to 1.87)
Injury	1.19 (0.35 to 4.03)	3.57 (1.41 to 9.05)	2.58 (1.14 to 5.81)	2.59 (1.32 to 5.09)	3.47 (1.42 to 8.49)
Hyperuricaemia	0.91 (0.38 to 2.16)	1.24 (0.40 to 3.84)	0.11 (0.01 to 0.97)	3.15 (1.65 to 6.00)	1.74 (0.37 to 8.26)

CI: confidence interval; NA: not applicable.
[a] Quintile 1 represents the poorest households and quintile 5 represents the wealthiest households.
[b] For each illness, we compared households that had experienced at least one episode with households that had experienced no episodes.
[c] No episodes of migraine/headache were reported in households in quintile 5.

varied by the type of illness that affected the household and the economic quintile to which the household belonged (Table 5). For example, in households belonging to the poorest quintile, one or more episodes of diabetes (rate ratio, RR: 2.37; 95% CI: 1.16–4.83), asthma (RR: 2.09; 95% CI: 1.28–3.42) or heart disease (RR: 2.24; 95% CI: 1.29–3.88) were associated with a significantly increased risk of catastrophic expenditure. The occurrence of at least one episode of diabetes increased the risk of catastrophic spending by households in quintiles 2 (RR: 2.13; 95% CI: 1.03–4.41) and 3 (RR: 2.85; 95% CI: 1.67–4.84) but did not significantly increase the risk of such spending by the wealthier households. Injury was associated with an elevated risk of catastrophic spending from the second to the fifth quintile (Table 5).

Discussion

This study provides evidence relating illnesses to catastrophic out-of-pocket expenditure on health care. More than one in every seven of the households that we investigated in urban areas of Kathmandu Valley reported catastrophic expenditure on health in the previous 30 days. In an earlier nationwide study, using the same definition, the corresponding proportion was only 5.9%.[4] However, our study focused on urban areas of Nepal, where health facilities are used more frequently than in rural areas.

After adjusting for confounders, we found that major noncommunicable diseases – such as diabetes, asthma and heart disease – were often associated with catastrophic spending in the poorest households. We also found that injury significantly increased the risk of catastrophic expenditure, irrespective of the household's economic status. A strong relationship between catastrophic expenditure and diabetes was also reported in a review of data from 35 low- and middle-income countries.[14] In a study in Viet Nam, the households of 27.5% of inpatients receiving treatment for injury had been faced with catastrophic expenditure.[29]

In Nepal there is scope for reducing the economic burden caused by noncommunicable diseases such as diabetes and heart disease. The control and management of the associated risk factors need to be improved, to prevent the onset of the diseases and any further complications. The Islamic Republic of Iran has successfully employed programmes of primary health care, targeted training of health workers and clear guidelines to improve diabetes screening and diagnosis at an early stage.[30] The regulation of tobacco and alcohol can also reduce the risks of several noncommunicable diseases. The government of Nepal banned tobacco and alcohol advertisements in 1996 and has taxed tobacco and alcohol products for many years. The raising of tobacco prices has been found to be an effective way of reducing tobacco consumption, especially among manual labourers and other low-income groups.[31] Such interventions can reduce the incidence of some noncommunicable diseases.[32]

It was not surprising to see injuries among the major causes of catastrophic household expenditure in Kathmandu Valley. Although drink-driving is banned in Nepal and the traffic police conduct regular breath tests among drivers in cities, road traffic accidents remain a major cause of injuries requiring treatment in Nepal – as in south-eastern Asia.[33] In the absence of any general health insurance scheme, serious injury is likely to be associated with unexpected and large household expenditures. The government of Nepal should consider intensifying programmes for the prevention of traffic accidents and injuries in urban municipalities, through road and workplace safety measures such as speed limits and traffic signals.[34]

As a policy priority – for the prevention of health-care-related financial catastrophe in the urban households of Nepal – some form of broad-based risk pooling needs to be encouraged.[6,35,36] The introduction of such a financial protection mechanism may be challenging in Nepal, and with limited fiscal space, a rapid increase in Nepal's national health expenditure seems unlikely, at least in the short-term.[37] However, a phased introduction of health insurance or other forms of financial protection may be feasible.[7,38]

This study has several limitations. First, it was conducted between November 2011 and January 2012 – i.e. in mid-winter. The timing of the survey may well have influenced the recorded prevalence of communicable diseases such as colds, which tend to be more common in winter than in summer. However, in a national survey that took place in 2010–2011 – the Nepal Living

Standard Survey – cold/cough/fever was found to be the most prevalent illness throughout the year.[39] Other studies have also reported a fairly consistent prevalence of diabetes and hypertension in urban Nepal.[40,41]

The second limitation is that our results are based on self-reported health spending. We assumed that poor households might use coping strategies to minimize their expenditure on health care – e.g. avoiding consultations with physicians, skipping dosages or selecting cheaper medicines. In the treatment of chronic illnesses, non-adherence to prescribed medications is common.[42,43] Although respondents were asked whether, to minimize costs, they had ever skipped a dosage, delayed seeking new supplies of medicines or reduced doses, we were not able to quantify how much the respondents may have saved from such cost aversion. Therefore, although, for each of the commonly reported illnesses, we estimated the treatment costs paid by an affected household, these estimates may have been smaller than the full costs of a standard regimen of treatment.

Despite its limitations, this population-based study demonstrates associations between injury and several major diseases and the incidence of catastrophic household expenditure on health care. By identifying the economic burden posed by each type of common illness, it should be possible to prioritize health interventions that are most likely to protect households from impoverishment – even in resource-limited settings.

In Nepal, there is an urgent need to initiate programmes for the control and management of the diseases associated with catastrophic household spending and the prevention of road traffic and other injuries. A phased introduction of health insurance, initially designed to cover or subsidize the costs of care for diabetes and heart disease, should be considered in Nepal. The national government needs to take extra measures to protect the poorest in its population from financial catastrophe. ■

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ملخص

معدل حدوث الإنفاق الأسري الكارثي على الصحة في نيبال والاعتلالات المرتبطة به: دراسة استقصائية متعددة القطاعات

الغرض تحديد معدل حدوث الإنفاق الأسري الكارثي على الصحة في نيبال – والاعتلالات الشائعة المرتبطة بهذا الإنفاق – في نيبال.

الطريقة قمنا بإجراء دراسة استقصائية سكانية متعددة القطاعات في خمس بلديات في كاتماندو فالي في الفترة من تشرين الثاني/ نوفمبر 2011 إلى كانون الثاني/ يناير 2012. وقد اعتبر الإنفاق من المال الخاص على الصحة خلال الثلاثين يوماً السابقة الذي تجاوز ٪10 من مجموع الإنفاق الأسري على مدار الفترة ذاتها كارثياً، لكل أسرة خضعت للدراسة الاستقصائية. وقمنا بتقدير معدل حدوث الإنفاق الصحي الكارثي وكثافته. وقمنا بتحديد الاعتلالات المرتبطة على نحو أكثر شيوعاً بهذا الإنفاق باستخدام نموذج ارتداد بواسون، وتقييم توزيع الإنفاق عن طريق الشرائح الخمسية الاقتصادية للأسر باستخدام مؤشر التركيز.

النتائج بشكل عام، أبلغت 284 من أصل 1997 أسرة خضعت للدراسة في كاتماندو، أي 13.8 ٪ بعد التصحيح عن طريق أخذ عينات الوزن عن إنفاق صحي كارثي خلال الثلاثين يوماً السابقة للدراسة الاستقصائية. وتبين ارتباط هذا الإنفاق، بعد تصحيحه لأغراض تحديد العوامل المؤثرة، بالإصابات لا سيما تلك الناجمة عن حوادث المرور. وكان الإنفاق الكارثي بواسطة الأسر في أفقر شريحة خمسية مرتبطة بنوبة واحدة على الأقل من السكري أو الربو أو مرض القلب.

الاستنتاج ارتبط الإنفاق الأسري الكارثي على الصحة في إحدى المناطق الحضرية في نيبال في معظمه بالإصابات والأمراض غير السارية مثل السكري والربو. وينبغي تعزيز التدخلات في جميع أرجاء نيبال من أجل مكافحة الأمراض غير السارية وتدبيرها العلاجي وتوقي حوادث المرور. وينبغي أن يؤدي الاستخدام التدريجي للتأمين الصحي أيضاً إلى تقليل معدل حدوث الإنفاق الأسري الكارثي.

摘要

尼泊尔家庭灾难性卫生支出发生率和相关疾病：横断面调查

目的 确定尼泊尔灾难性卫生家庭支出发生率以及通常与这些支出相关的疾病。

方法 在 2011 年 11 月和 2012 年 1 月之间，我们在加德满都谷地五个自治市展开基于人口的横断面口调查。对于每个受调查的家庭，在调查前 30 天预算外卫生支出超过同一时期家庭总开支 10% 的支出被视为灾难性支出。我们估计灾难性卫生支出发生率和强度。我们使用泊松回归模型识别与此类支出最常相关的疾病，并通过集中指数按照家庭经济五分位数评估支出的分配。

结果 总体来看，加德满都 1997 户受研究的家庭有 284 户（即抽样权重调整后 13.8% 的家庭）报告在调查前 30 天有灾难性卫生支出。调整混杂因素后，发现这部分支出与损伤有关，特别是道路交通事故引起的伤害。10% 最贫穷的家庭中，其灾难性支出与糖尿病、哮喘或心脏病当中至少一种疾病的发病期有关。

结论 在尼泊尔市区，家庭灾难性卫生支出主要与损伤和非传染性疾病相关，如糖尿病和哮喘。在尼泊尔全国，应该提升控制和管理非传染性疾病和预防道路交通事故的干预措施。分阶段引入医疗保险也将降低灾难性家庭支出的发生率。

Résumé

Dépenses catastrophiques de santé des ménages au Népal: une enquête transversale

Objectif Déterminer l'incidence de dépenses catastrophiques de santé des ménages – et les maladies généralement associées à ces dépenses – au Népal.

Méthodes Nous avons mené une enquête transversale sur la population dans cinq municipalités de la Vallée de Katmandu entre novembre 2011 et janvier 2012. Pour chaque ménage étudié, les dépenses de santé qui sont restées à la charge du ménage dans les 30 jours précédents et qui ont dépassé 10% des dépenses totales du ménage au cours de la même période, ont été considérées comme étant catastrophiques. Nous avons estimé l'incidence et l'intensité des dépenses catastrophiques de santé. Nous avons identifié les maladies les plus généralement associées avec de telles dépenses en utilisant un modèle de régression de Poisson et évalué la distribution des dépenses par quintile économique des ménages en utilisant l'indice de concentration.

Résultats Dans l'ensemble, 284 des 1 997 ménages étudiés à Katmandu, c.-à- d. 13,8% après correction par pondération de l'échantillonnage, ont signalé des dépenses catastrophiques de santé dans les 30 jours qui ont précédé l'enquête. Après ajustement pour les variables confusionnelles, nous avons pu montrer que ces dépenses étaient associées à des blessures, en particulier celles causées par les accidents de la route. Les dépenses catastrophiques des ménages faisant partie du quintile le plus pauvre étaient associées à au moins un épisode de diabète, d'asthme ou de maladie cardiaque.

Conclusion Dans une zone urbaine du Népal, les dépenses catastrophiques de santé des ménages furent principalement associées à des blessures et à des maladies non transmissibles comme le diabète ou l'asthme. À travers tout le Népal, des interventions pour le contrôle et la gestion des maladies non transmissibles et pour la prévention des accidents de la route devraient être encouragées. Une introduction progressive de l'assurance maladie devrait également réduire l'incidence des dépenses catastrophiques des ménages.

Резюме

Распространение заболеваний в результате катастрофических расходов домашних хозяйств на медицинские услуги в Непале: перекрестное исследование

Цель Определить влияние катастрофических расходов на медицинские услуги в Непале и выявить, какие заболевания в большинстве случаев связаны с этими расходами, а также частоту возникновения этих заболеваний.

Методы С ноября 2011 г. по январь 2012 г было проведено перекрестное исследование среди населения пяти муниципальных образований Долины Катманду. Расходы на медицинские услуги для всех домашних хозяйств, принимавших участие в исследовании, признавались катастрофическими, если за предыдущие 30 дней они превышали 10% от общих расходов домашнего хозяйства за этот период.. Были оценены влияние и величина катастрофических расходов на медицинские услуги. Были определены заболевания, которые чаще всего связаны с такими расходами, при помощи модели пуассоновской регрессии и оценено распределение расходов по экономическим квинтилям домашних хозяйств при помощи индекса концентрации.

Результаты Всего 284 из 1997 домашних хозяйств в Катманду, участвовавших в исследовании, что составляет 13,8% после поправки на размер выборки, сообщили о катастрофических расходах на медицинские услуги за 30 дней, предшествовавших опросу. После поправки с учетом возможных неизвестных факторов эти расходы оказались связаны с травмами, в особенности полученными в результате дорожных происшествий. В домашних хозяйствах, относящихся к самой бедной части населения, были отмечены как минимум по одному случаю диабета, астмы или сердечно-сосудистых заболеваний.

Вывод В городских районах Непала катастрофические расходы домашних хозяйств на медицинские услуги преимущественно связаны с травмами и неинфекционными заболеваниями, такими как диабет и астма. На всей территории Непала должны быть предприняты оперативные меры по контролю и профилактике неинфекционных заболеваний и предотвращению дорожно-транспортных происшествий. Поэтапное внедрение медицинского страхования должно снизить численность катастрофических расходов домашних хозяйств на медицинские услуги.

Resumen

Incidencia del gasto catastrófico por motivos de salud y enfermedades asociadas con el mismo en los hogares en Nepal: un estudio transversal

Objetivo Determinar la incidencia del gasto catastrófico por motivos de salud de los hogares y las enfermedades generalmente asociadas con dichos gastos en Nepal.

Métodos Se llevó a cabo una encuesta transversal de la población en cinco municipios del Valle de Katmandú entre noviembre de 2011 y enero de 2012. Para cada hogar encuestado, se consideró catastrófico cualquier gasto de desembolso directo por motivos de salud en los últimos 30 días que hubiera excedido el 10 % del gasto total del hogar durante el mismo periodo. Se estimó la incidencia y el grado de los gastos catastróficos por motivos de salud. Se identificaron las enfermedades asociadas con mayor frecuencia con dichos gastos mediante un modelo de regresión de Poisson y se evaluó la distribución del gasto por quintil económico de los hogares mediante el índice de concentración.

Resultados En total, se descbrió que 284 de los 1997 hogares estudiados en Katmandú, es decir, un 13,8 % tras el ajuste mediante el muestreo de peso, tuvieron que hacer frente a gastos catastróficos por motivos de salud en los 30 días anteriores a la encuesta. Después del ajuste por factores de confusión, se halló que dicho gasto estaba asociado a lesiones, sobre todo aquellas derivadas de accidentes de tráfico y, en los hogares pertenecientes al quintil más pobre, con al menos un episodio de diabetes, asma o enfermedades cardíacas.

Conclusión En un área urbana de Nepal, el gasto catastrófico de los hogares por motivos de salud estuvo en su mayoría asociado a lesiones y a enfermedades no transmisibles como la diabetes y el asma. Es necesario fomentar las intervenciones para el control y el manejo de las enfermedades no transmisibles, así como la prevención de los accidentes de tráfico en todo Nepal. La introducción gradual de un seguro médico también podría reducir la incidencia de los gastos catastróficos de los hogares.

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添付資料１

介護サービス市場における供給者誘発需要仮説の検証

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抄録

【背景】介護保険制度では、居宅介護支援事業所は中立・独立的なエージェントとして利用者のサービス選択を補佐する機能することが求められている。しかし、その約 90%は居宅サービス事業所（供給者）を併設しており、事業所の収益性を考慮した誘発需要のインセンティブを持つ可能性がある。しかし先行研究では、居宅介護支援事業所と居宅サービス事業所の経営主体上の独立性を考慮に入れた分析は行われていない。

【目的】実質的に通所介護の報酬が切り下げられた平成 24 年年度の介護報酬改定を自然実験とし、居宅介護支援事業所と通所介護事業所の経営主体上の独立性により供給者行動に異なる影響が及んだか否かを検証する。

【方法】平成 23 年 4 月から平成 25 年 3 月までの介護給付費実態調査の個票データと平成 23 年度介護サービス施設・事業所調査の個票を突合し、居宅介護支援事業所を利用している要介護高齢者 366,676 例を本研究の分析対象とした。分析モデルは通所介護利用の有無、1 か月当たりの通所介護利用日数、1 日当たりの通所介護単位数（サービス提供時間に応じた基本サービス部分と入浴などのサービス提供による加算部分）をアウトカムとし、通所介護事業所併設ダミー、介護報酬改定ダミー、それらの交差項を説明変数とした 3 つのパートからなるパネル推定を行った。さらに、1 か月当たりの居宅サービス単位数をアウトカムとした推計を行った。

【結果】パネル推計の結果、通所介護利用（通所介護利用の有無、利用日数、加算部分）

について、介護報酬改定ダミーは有意に正の値を示したが、通所介護事業所併設ダミーと介護報酬改定ダミーの交差項は有意に負の値を示した。一方で、1 か月当たりの居宅サービス単位数をアウトカムとした場合、介護報酬改定ダミー、通所介護事業所併設ダミーと介護報酬改定ダミーの交差項はともに有意に正の値を示した。

【考察】介護報酬改定後に通所介護利用割合や 1 か月当たりの利用日数は増加したが、通所介護併設型の居宅介護支援事業所を利用している要介護高齢者は、非併設型利用者に比べ、その大きさが小さいことが示され、負の供給者誘発需要が確認された。一方で、介護報酬改定後のすべての居宅サービス単位数の増加は、通所介護併設型利用者で大きいことから、通所介護の介護報酬切り下げによる収入の低下を、他の介護サービスで補った可能性が示唆された。

１．背景

高齢化や核家族化の進行等により、要介護者を社会全体で支え合う仕組みとして 2000 年に介護保険制度が導入された[1]。介護保険制度では、利用者が自らサービスの種類や事業者を選んで利用することが出来る。また、要介護高齢者が適切なサービスを利用できるようにするため、専門的な知識を有する介護支援専門員（ケアマネージャー）が介護サービスの利用計画（以下、ケアプラン）を作成し、要介護高齢者や家族介護者の意思決定を援助している[2, 3]。そのため、介護支援専門員は中立性・独立性を持つエージェントとしての機能を持つことが求められている。しかし、介護支援専門員が所属している居宅介護支援事業所の多くは居宅サービス事業所を併設しており[i]、「利用者に対して公平な情報提供を行うインセンティブがあるかどうか疑問に残る（鈴木, 2002）」と指摘されている[4]。また、居宅介護支援事業所と居宅サービス事業所の併設の有無で、利用者のサービス利用に大きな差があるとの報告[5]や、介護支援専門員に対する調査において、ケアプラン作成における公平・中立に反する不適切な事例があると指摘されている[6]。

このことから、居宅サービス事業所を併設している居宅介護支援事業所は、経営状況が思わしくない場合、同一法人もしくは併設事業所のサービスを過剰に提供することで、事業所の収支を改善させようとするインセンティブを持つ可能性がある。つまり、地域の介護サービス事業所の増加や介護報酬の引き下げによる所得が低下した場合、介護サービス需要を誘発する可能性が考えられる。

これは供給者誘発需要仮説と呼ばれる議論であり、McGuire (2000)は「Physician-induced demand (PID) exists when the physician influences a patient’s demand for care against the physician’s interpretation of the best interest of the patient.」と定義している[7]。この誘発需要の存在については医療分野において数多くの実証分析が行われており、医療供給密度と医療

[ii]居宅介護支援事業所に対する調査では、約 90%の事業所が何らかの併設サービスを有している（三菱総合研究所, 2015）

費の関係の検証、診療費支払いの低下といった医療制度改革を用いた誘発需要の検証が行われている[8−15]。

一方、介護保険分野においては山内 (2004) [16]、湯田 (2005) [17]、Noguchi and Shimizutani (2009) [18] が供給者誘発需要の検証を行っている。これら先行研究は介護事業者密度（要介護高齢者当たりの介護事業者数）の変化が誘発需要を引き起こすかどうかを検証しており、山内(2004)は誘発需要とアクセスコストの低下などによる要介護高齢者主体の需要を識別せずに検証を行っている一方、湯田(2005)、Noguchi and Shimizutani (2009)は介護需要を要介護高齢者主体的な需要（要介護高齢者要因）と供給者の裁量に左右される需要（供給者要因）に分けて分析を行う two-part model を応用した検証を行っている。その結果、山内 (2004)は介護事業者数の増加が誘発需要を引き起こす可能性を示し、湯田(2005)、Noguchi and Shimizutani (2009)は介護事業者数の増加が介護費用に与える影響は限定的であるという結果を得ている。しかし、介護保険制度では、居宅介護支援事業所がケアプランを作成するため、介護サービスを利用するかどうかについても供給者の裁量に左右される可能性があると考えられる。このことから、two-part model を用いることで、供給者主導の要因と要介護高齢者主導の要因を識別できるという点に関しては疑問が残る。また、これら先行研究は居宅介護支援事業所と居宅サービス事業所の経営主体上の独立性を考慮に入れた分析は行われていない。

また先行研究では、訪問系サービス、通所系サービスなど、個々のサービスを区別した検証は限られている。平成 24 年度の介護報酬改定で通所介護の介護報酬が実質的に切り下げられており [19]、通所介護の供給行動に影響を与えた可能性がある。一方、通所介護に次いで受給者数の多い訪問介護 [20] は、サービスの提供が厳格化されていること [21] や、自宅で行われる訪問系サービスは通所系サービスに比べ情報の非対称性が小さいと考えられることから、誘発需要は生じにくいと考えられる。

そこで本研究では、平成 24 年度の介護報酬改定を自然実験とし、居宅介護支援事業所と

通所介護事業所の経営主体上の独立性により供給者行動に異なる影響が及んだか否かを検証することを目的とした。

以下、本稿の構成は以下の通りである。続く第 2 節では検証の背景として平成 24 年度の介護報酬改定と、居宅介護支援事業所と通所介護事業所の独立性について、第 3 節ではデータと対象者・変数について、第 4 節では供給者主導の要因を明らかにするための分析モデル、第 5 節では研究結果、第 6 節に結果の解釈と考察を示す。

２．検証の背景

１）平成 24 年度介護報酬改定

平成 24 年度の介護報酬改定により、通所介護のサービス提供の時間区分が改定された。例えば、通常規模型通所介護費で要介護 1 の場合、改定前は 677 単位/日（所要時間 6 時間以上 8 時間未満の場合）であったのが、改定後は 602 単位/日（所要時間 5 時間以上 7 時間未満の場合）・690 単位/日（所要時間 7 時間以上 9 時間未満の場合）となった。改定前後で時間区分が異なるが、改定前の調査ではサービス提供時間は平均 6.2 時間であることから[22]、改定前後で同じ時間のサービスを提供した場合、改定後には改定前に比べ、介護報酬が約 10%の減少、時間を延長した場合でも約 3%の増加に留まっており、実質的には介護報酬は切り下げられたといえる。

２）居宅介護支援事業所の特性（独立型・併設型）

居宅介護支援事業所の多くが居宅サービス事業所を併設しており、2013 年の調査では併設サービスを持っていない独立型の事業所は約 10%である[5]。また、通所介護事業所を併設している居宅介護支援事業所は 50.8%、訪問介護は 46.5%、通所リハビリテーションは 16.7%となっている[5]。

３．データと対象者・変数

１）データ

使用したデータは平成 23 年 4 月から平成 25 年 3 月までの介護給付費実態調査の個票[20]と、平成 23 年度の介護サービス施設・事業所調査の個票[23]である。

介護給付費実態調査は介護サービスに係る給付費の状況を把握し、介護報酬の改定など、介護保険制度の円滑な運営及び政策の立案に必要な基礎資料を得ることを目的としたもので、各都道府県国民健康保険団体連合会が審査したすべての介護給付費明細書、給付管理票を集計対象としている。介護給付費明細書は居宅サービス事業所が月ごとに作成した性・年齢・要介護(要支援)状態区分・サービス種類別単位数・回数等の情報、給付管理票は居宅介護支援事業所が月ごとに作成した性・年齢・要介護(要支援)状態区分・サービス種類別計画単位数等が調査事項となっている。

介護サービス施設・事業所調査は、全国の介護サービスの提供体制、提供内容を把握することを目的とした介護サービス事業所に対する全数調査であり、介護サービス事業所の法人名や施設名、活動状況などが調査事項となっている。調査時期は各年 10 月となっており、本研究では平成 23 年 10 月 1 日時点の居宅介護支援事業所、居宅サービス事業所の情報を使用した[ii]。政府統計個票データの利用に当たっては統計法に基づき個票利用申請・許可された。

２）対象

分析対象選択の流れを **Figure 1** のフローチャートにまとめた。分析対象として、平成 23 年 4 月時点で、①要介護認定を受けている介護度 1~3 の 65 歳以上の高齢者で、②施設に入所していないものを選択した（N= 3,799,257）。除外基準としては分析対象期間である平成 23 年 4 月から平成 25 年 3 月までの間に、①介護保険施設に入所したもの、②要支援 1~2、

[ii] 平成 23 年度介護サービス施設・事業所調査の居宅介護支援事業所に対する調査票の回収率は 85.4%（28,628 事業所/33,517 事業所）であった[15]。

もしくは要介護 4~5 に区分変更したもの、③他の市区町村（保険者）への転居や死亡などにより個人の追跡が困難なもの、④ケアプランを作成する居宅介護支援事業所を利用していない、⑤居宅介護支援事業所を変更したもの[iii]とし、これらの基準に合致した 416,462 例を分析対象とした。さらに、平成 23 年度の介護サービス施設・事業所調査から抽出した居宅介護支援事業所情報と突合可能であった例から欠損値がある例を除外した 366,676 例を本研究の最終的な分析対象とした。

3）変数

アウトカム変数（通所介護の利用）

①通所介護利用の有無、②1 か月当たりの通所介護利用日数、③1 日当たり通所介護単位数（サービス提供時間に応じた基本サービス費[iv]と入浴などのサービス提供による加算[v]）をアウトカムとした。

また、介護報酬改定が他の居宅サービスの利用に与えた影響を検証するために、1 か月当たりの居宅サービス単位数（全サービスの合計）を副次的アウトカムとした。

説明変数

要介護高齢者変数として、介護給付費実態調査の個票より抽出した、性・年齢・要介護状態区分、ケアプランを作成している居宅介護支援事業所情報を用いた。

居宅介護支援事業所変数は、介護サービス施設・事業所調査の個票から抽出し、固有 ID（事業所番号）を用いて、介護給付費実態調査と突合した。居宅介護支援事業所と通所介

[iii]居宅介護支援事業所の変更は要介護高齢者要因であると考えられるため、居宅介護支援事業所を変更した要介護高齢者は分析から除外した。

[iv]基本サービス費は要介護高齢者の介護度やサービス提供時間、通所介護事業所の規模によって異なる[11]が、介護度で補正すれば基本サービス費の増加はサービス提供時間を反映すると考えられる。

[v] 通所介護の加算は入浴介助加算や個別機能訓練加算、栄養改善加算などからなる。加算の取得要件として、人員配置やサービスの提供が定められている[11]。また、平成 24 年度の改定において、介護職員処遇改善のための加算が新たに創設された[11]。

護事業所の経営主体上の独立性を示す変数として、居宅介護支援事業所を所有している法人が、居宅介護支援事業所が所在する都道府県内に通所介護事業所を所有していれば「通所介護併設型」、同一都道府県内に通所介護事業所を所有していなければ「通所介護非併設型」とした。また、供給者行動に影響すると考えられる経営主体については、3 群（public non-for-profit, private non-for-profit, for-profit[vi]）に分類した[24]。さらに、通所介護の代替サービスと考えられる通所リハビリテーション事業所、訪問介護事業所の併設を居宅介護支援事業所変数として使用した。

４．分析モデル

１）介護報酬改定が通所介護の利用に与える影響

本研究では供給者誘発需要を検証する分析として、3 つのパートからなる以下のモデルを構築した[17,18,25]。

$$Y^1{}_{i,t} = \alpha_0 + \alpha_1 X_{i,t} + \alpha_2 I_{i,t} + \alpha_3 R_{i,t} + \alpha_4 I_{i,t} * R_{i,t} + \alpha_4 M_i + u_i + \varepsilon_{i,t} \quad \text{(1, first-part)}$$

$$Y^2{}_{i,t} = \beta_0 + \beta_1 X_{i,t} + \beta_2 I_{i,t} + \beta_3 R_{i,t} + \beta_4 I_{i,t} * R_{i,t} + \beta_4 M_i + u_i + \varepsilon_{i,t} \quad \text{(2, second-part)}$$

$$Y^3{}_{i,t} = \gamma_0 + \gamma_1 X_{i,t} + \gamma_2 I_{i,t} + \gamma_3 R_{i,t} + \gamma_4 I_{i,t} * R_{i,t} + \gamma_4 M_i + u_i + \varepsilon_{i,t} \quad \text{(3, third-part)}$$

アウトカムとして、それぞれY^1は通所介護利用の有無（first-part）、Y^2は 1 か月当たりの通所介護利用日数（second-part）、Y^3は 1 日当たり通所介護単位数（基本サービス部分・加算部分）（third-part）とした。説明変数は$X_{i,t}$に要介護高齢者特性として性・年齢・要介護状態区分を調整した。さらに、$I_{i,t}$はケアプランを作成している居宅介護支援事業所特性として通所介護併設ダミー（0: 通所介護非併設型、1: 通所介護併設型）、$R_{i,t}$は介護報酬改定ダミー（0: 平成 24 年介護報酬改定前、1: 介護報酬改定後）、通所介護併設ダミーと介護報酬

[vi] public non-for-profit: 地方行政、社会福祉協議会
private non-for-profit: 社会福祉法人、医療法人、社団・財団法人（公益・一般）、農協、生協、NPO

改定ダミーの交差項、また、月別の変動を調整するための月次ダミーM_iを説明変数としたモデルを構築した。

First-part は分析対象者すべて（N=366,676）を対象に、Second-part, Third-part は 24 か月継続して通所介護サービスを利用しているもの（N=177,247）を対象に分析を行った。

本研究は個人別の時系列データであるため、推定はパネル推定とした。また、モデルの選択には Breusch–Pagan 検定、Hausman 検定を用いた。

本研究では識別性の問題に対処した供給者誘発需要について通所介護併設ダミーと介護報酬改定ダミーの交差項の係数α_4、β_4、γ_4から得られると考えられる。通所介護非併設型の居宅介護支援事業所を利用している場合、介護報酬改定が通所介護の利用に与える影響は要介護高齢者主導の需要の変化と考えられる。これは、通所介護非併設型であれば、通所介護の介護報酬が低下したとしても、それによる収入の低下を補うため、通所介護の利用を変化させるインセンティブは発生しないと考えられるためである。一方、通所介護併設型の場合、介護報酬改定後の変化は自己負担の低下や通所介護時間の延長などによる要介護高齢者主導の需要と供給者側主導の需要が合わさったものと考えられる。そこで、この両者の差の推計、上記モデルでは通所介護併設ダミーと介護報酬改定ダミーの交差項の係数が供給者主導を示す結果となる。

また、介護報酬改定が介護サービス利用全体に与える影響を検証するために、1 か月当たりの居宅サービス単位数をアウトカムとしたパネル推定を追加解析として行った。

データの解析には STATA 14 (StataCorp, College Station, TX, USA) を用いた。

５．結果

１）記述統計

Table 1 に対象者の平成 24 年 4 月時点の記述統計を居宅介護支援事業所の特性別（通所介

護併設群・非併設群）に示す。全体の 63.6%が通所介護併設型の居宅介護支援事業所を使用していた。通所介護併設型を利用している要介護高齢者（以下、通所介護併設群）は、通所介護を併設していない要介護高齢者（以下、通所介護非併設群）に比べ、年齢が高く、女性割合が低く、介護度が軽度である割合が高かった。通所介護の利用割合、1 か月当たりの通所介護利用日数・1 日当たり通所介護単位数（基本サービス部分・加算部分）の平均値の経時変化を居宅介護支援事業所の特性別（通所介護併設群・非併設群）に **Figure 2~5** 示す。通所介護併設群では、通所介護非併設群に比べ通所介護の利用割合が約 20%程度高かった。通所介護を利用している高齢者に限定して見ると、通所介護併設群が通所介護非併設群に比べ、1 か月当たりの通所介護利用日数、1 日当たりの通所介護単位数（加算部分）が多く、1 日当たりの単位数（基本サービス部分）は少なかった。

Table 2 に介護サービス施設・事業所調査より抽出した居宅介護支援事業所の特性を示す。事業所全体の 46.0%が通所介護併設型の居宅介護支援事業所であった。通所介護併設型の居宅介護支援事業所は経営主体が for-profit である割合が高く、通所リハビリテーション事業所を併設している割合が低く、訪問介護事業所を併設している割合が高かった。

２）モデル分析（通所介護の利用に与える影響）

Table 3 に通所介護利用の有無をアウトカムとした first-part の推計結果を示す。Breusch and Pagan 検定、Hausman 検定の結果、固定効果モデルが選択された。通所介護利用に対する介護報酬改定ダミーの係数は 0.016 と有意に正の値を示したが、通所介護併設ダミーと介護報酬改定ダミーの交差項は-0.010 であり有意に負の値を示した。このことから介護報酬改定後に通所介護の利用割合は増加したが、その影響は通所介護併設型で小さかったことが示された。また、プーリングモデル、ランダム効果モデルの通所介護併設ダミーは正の値を示した。

Table 4~6 にアウトカムを 1 か月当たりの通所介護利用日数とした second-part の推計結果、

1 日当たり通所介護単位数（基本サービス部分・加算部分）とした third-part の推計結果を示す。Breusch and Pagan 検定、Hausman 検定の結果、すべてのモデルで固定効果モデルが選択された。1 か月当たりの通所介護利用日数と 1 日当たり通所介護単位数（加算部分）に対する介護報酬改定ダミーの係数はそれぞれ 0.529、10.325 と有意に正の値を示したが、通所介護併設ダミーと介護報酬改定ダミーの交差項はそれぞれ-0.039、-0.321 と有意に負の値を示した。一方で、1 日当たり通所介護単位数（基本サービス部分）に対する介護報酬改定ダミーの係数は-0.764、通所介護併設ダミーと介護報酬改定ダミーの交差項は-0.492 であり、ともに有意に負の値を示した。

Table 7 に介護報酬改定が 1 か月当たりの居宅サービス単位数をアウトカムとした推計結果を示す。Breusch and Pagan 検定、Hausman 検定の結果、固定効果モデルが選択された。1 か月当たりの居宅サービス単位数に対する介護報酬改定ダミーの係数は 691.0 と有意に正の値を示し、通所介護併設ダミーと介護報酬改定ダミーの交差項も 136.5 と有意に正の値を示す結果が得られた。

６．考察

本研究では、介護サービス市場における供給者誘発需要の検証するため、平成 24 年度の介護報酬改定を自然実験とし、居宅介護支援事業所と通所介護事業所の経営主体上の独立性による供給者行動の違いをパネル推定により明らかにした。

その結果、改定前から通所介護併設型の居宅支援事業所を利用している要介護高齢者では、非併設型利用者に比べ、通所介護を利用している割合は高かった。また介護報酬改定後には通所介護利用割合や 1 か月当たりの通所介護利用日数は増加したが、通所介護併設型利用者では、非併設型利用者に比べ、その大きさが小さいことが示された。これらのことから、通所介護併設型の居宅介護支援事業所は通所介護を利用させる傾向にあるが、介護報酬改定後は通所介護の利用を抑制している可能性が示唆された。また、1 日当たりの通

所介護単位数（基本サービス部分・加算部分）に与える影響を検証した結果からは、改定後に供給者主導のサービス提供時間の延長や、入浴などのサービス提供を増加させるといった行動は確認されず、これらサービスを抑制する方向に働いていた。

湯田(2005)は都道府県単位のパネルデータ分析により、通所介護事業者密度が通所介護の受給率や 1 件当たりの費用と正の関連があることを示しており、通所介護については供給者誘発需要が存在することを否定していない。これは、介護報酬改定前において、通所介護併設型が非併設型に比べ、通所介護の利用割合や 1 か月当たりの利用日数が多い、つまり供給者主導の要因がある可能性を示した本研究の結果と一致している。

また本研究では、実質的な通所介護報酬の切り下げに対し、通所介護併設型は通所介護の利用を抑制する負の供給者誘発需要が確認された。医療の分野では、自然分娩と帝王切開の報酬差が高い帝王切開率につながるとの報告 [11] や薬剤の支払い額の変更に伴い利益率の高い薬剤に変更する [27] といった報告がある。また、Chou らは台湾における医薬分業政策により、薬剤の費用は低下したが、総医療費は変化がなかったことを示している [15]。これらのことから、介護サービスにおいても、通所介護の介護報酬の低下に対し、通所介護の利用割合や利用日数を抑制し、他の居宅サービスの利用を促した可能性がある。1 か月当たりの居宅サービス単位数をアウトカムとした本研究の推計結果では、介護報酬改定後の居宅サービス単位数の増加は非併設型に比べ併設型の方が大きく、正の供給者誘発需要が確認された。このことから、通所介護併設型は通所介護の実質的な引き下げによって減少した収入を他のサービスの提供量を増加させることで補った可能性が考えられる。さらに、1 か月当たりの居宅サービス単位数には負の誘発需要が確認された通所介護の利用も含まれていることから、通所介護併設型は減少した収入を補うだけでなく、それ以上のサービスを提供した可能性も示された。

本研究の強みとしては、わが国の代表する介護給付データを用いている点、介護報酬改定といった外生的な要因を自然実験とし、居宅介護支援事業所と通所介護事業所の経営主

体上の独立性を分析に用いることで、要介護高齢者主導の要因と供給者主導の要因を識別した点である。しかしながら、本研究の限界としていくつかの点が挙げられる。

まず、要介護高齢者の特性や家族状況といった介護サービスの利用に影響を与える要因の補正を十分に行えていないため、通所介護併設が通所介護利用そのものに与える影響については因果の逆転に対応できてない可能性がある。

2 点目の限界として、通所介護以外の介護サービスに与える影響について十分に検証できていない点が挙げられる。居宅サービス単位数は介護報酬改定後に増加していることは示したが、介護報酬改定後の個々のサービス利用の変化や、通所介護サービス利用の変化が他の介護サービス（代替サービス・補完サービス）に与える影響は明らかになっていないため、居宅介護支援事業所が併設している他のサービスを考慮にいれた検証を行う必要である。

最後に要介護高齢者の健康に与える影響を検証していない点である。ただ、本研究は介護報酬改定後 1 年までしか追跡していない点や、介護給付費実態調査では要介護高齢者の重症度を示す指標が介護度のみであることから、要介護高齢者の健康に与える影響を明らかにするためには、追加的な研究が必要となると考えられる。

政策的意義

本研究は介護報酬の改定が通所介護の利用に与える影響が、居宅介護支援事業所と通所介護事業所の経営主体上の独立性により異なることを明らかにした。このことから、情報の非対称性が小さいと考えられている介護サービスであっても供給者主導の需要があることが示され、併設サービスについてはケアプランが適切に作成されているかを評価する必要があると考えられる。

居宅介護支援の介護報酬では、居宅介護支援を公正中立に機能させるために、特定の事業所に集中して訪問介護や通所介護、福祉用具貸与サービスを利用すると居宅介護支援費

が減算されている[19]。しかし、本研究の結果からは、供給者主導の需要は抑制的に働く可能性があること、また、通所介護の介護報酬の切り下げが他の介護サービスの需要を誘発する可能性があることが示され、訪問介護や通所介護を特定の事業所に集中させることを防ぐだけでは居宅介護支援の公正中立を保つことができない可能性が示唆された。

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Figure 1 対象者選択の流れ

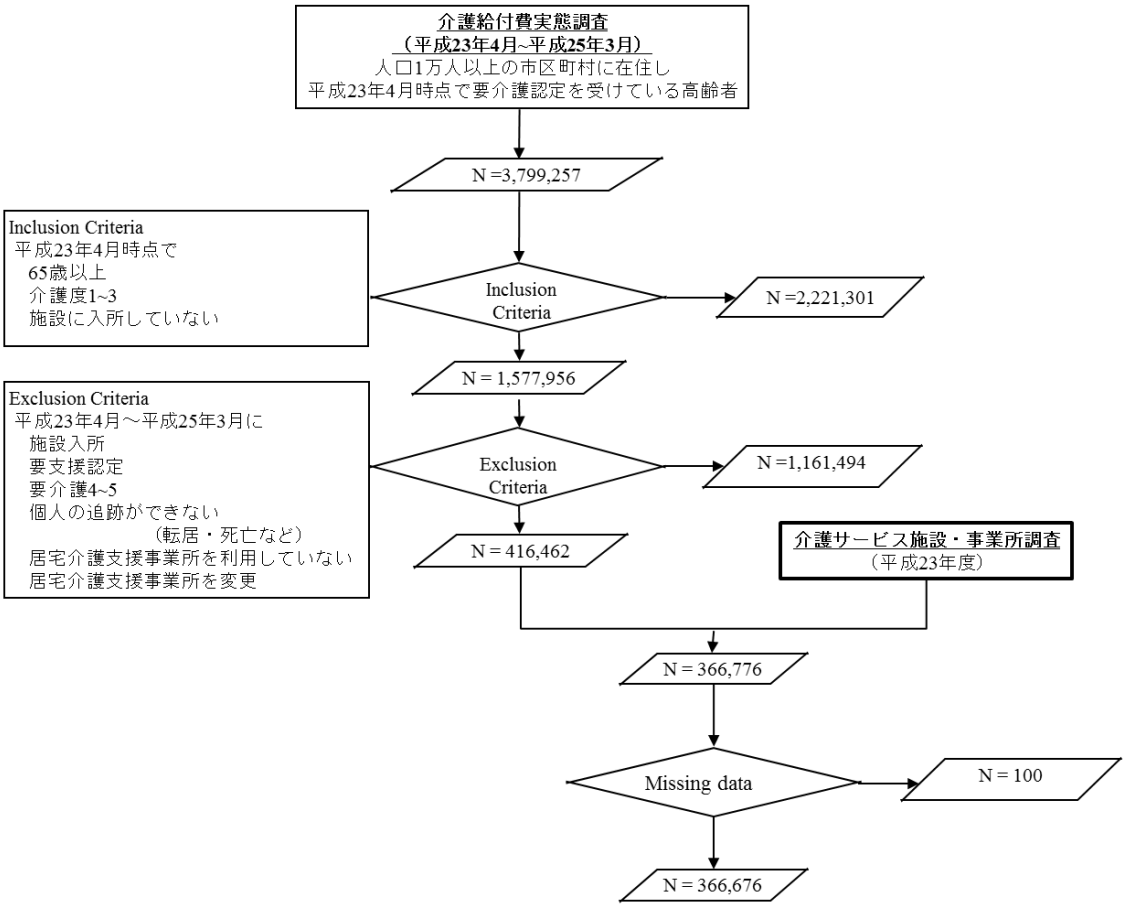

Fig. 2 通所介護利用割合の経時変化

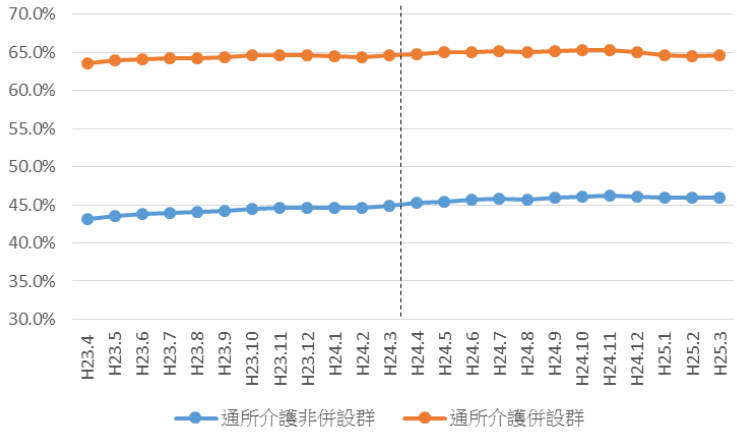

Fig. 3　1 か月当たりの通所介護利用日数

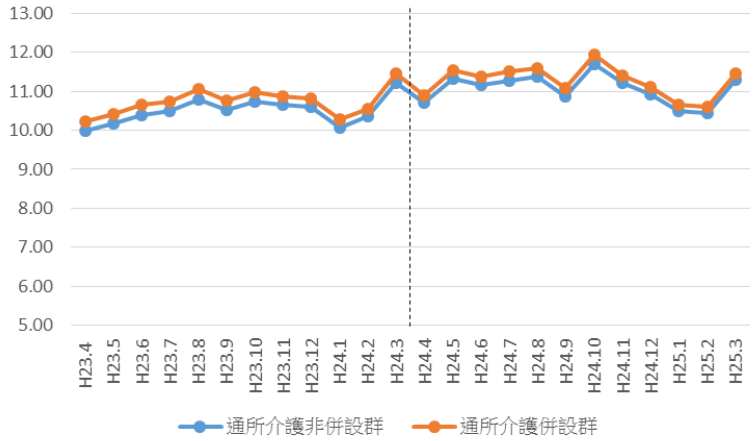

Fig. 4　1 日当たり通所介護単位数（基本サービス部分）

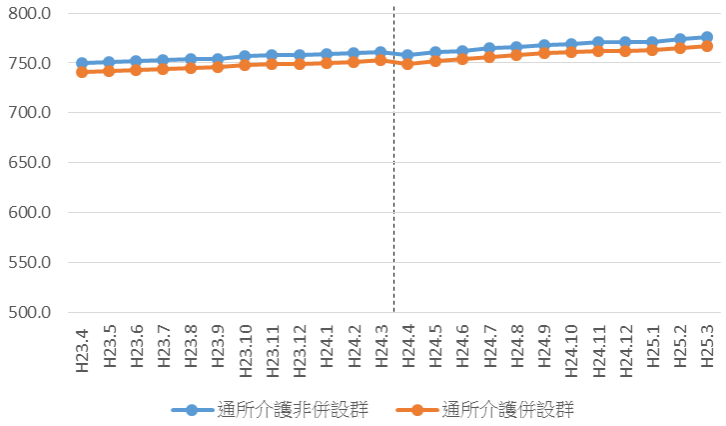

Fig. 5　1 日当たり通所介護単位数（加算部分）

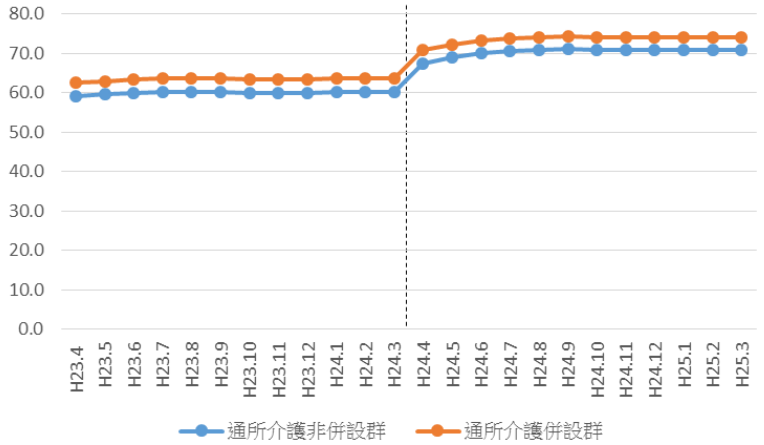

Table 1 対象者の記述統計（平成 23 年 4 月時点）

	通所介護非併設群 N=133,395	通所介護併設群 N=233,281	P value
年齢　(mean±SD, years)	81.7±7.4	82.5±7.3	P < 0.01
性別，女性	68.9%	66.4%	P < 0.01
介護度			
要介護 1	41.4%	44.3%	P < 0.01
要介護 2	40.4%	39.2%	
要介護 3	18.3%	16.5%	
通所介護利用，あり	43.1%	63.6%	P < 0.01
すべての居宅サービス単位数 (mean±SD, units/month)	7507±5878	8066±5830	P < 0.01
経営主体			
public non-profit provider	7.7%	11.4%	P < 0.01
private non-profit provider	54.8%	65.9%	
for-profit provider	37.5%	22.8%	
通所リハビリテーション併設，あり	37.0%	18.2%	P < 0.01
訪問介護併設事業所，あり	49.3%	72.6%	P < 0.01
通所介護利用高齢者	(N=57,473)	(N=148,248)	
通所介護利用日数 (mean±SD, days/month)	9.5±5.2	9.8±5.3	P < 0.01
通所介護単位数・基本サービス部分 (mean±SD, units/day)	747.9±132.8	740.2±121.9	P < 0.01
通所介護単位数・加算部分 (mean±SD, units/day)	58.6±27.1	62.2±26.4	P < 0.01

*群間差の検定にはカテゴリー変数の場合はχ2 検定を、連続変数には t 検定を用いた。

*public non-profit provider: 地方公共団体、社会福祉協議会

private non-profit provider: 社会福祉法人、医療法人、社団・財団法人（公益・一般）、農協、生協、NPO

Table 2 居宅介護支援事業所の記述統計

	通所介護非併設 N=12,748	通所介護併設 N=14,957	P value
経営主体			
public non-profit provider	5.7%	9.1%	P < 0.01
private non-profit provider	44.1%	57.2%	
for-profit provider	50.3%	33.8%	
通所リハビリテーション併設あり	24.5%	13.5%	P < 0.01
訪問介護併設あり	45.9%	64.4%	P < 0.01

* public non-profit provider: 地方公共団体、社会福祉協議会

* private non-profit provider: 社会福祉法人、医療法人、社団・財団法人（公益・一般）、農協、生協、NPO

Table 3 通所介護利用の有無に与える影響; First-part（linear model）

	pooling model		random effect model		fixed effect model	
	coef.	P value	coef.	P value	coef.	P value
性別 (1=女性)	0.048	P<0.01	0.057	P<0.01	omitted	
年齢	0.007	P<0.01	0.005	P<0.01	0.000	0.67
介護度						
要介護 1						
要介護 2	-0.032	P<0.01	0.003	P<0.01	0.003	P<0.01
要介護 3	-0.017	P<0.01	-0.002	P<0.01	-0.002	P<0.01
通所介護併設ダミー	0.194	P<0.01	0.196	P<0.01	omitted	
介護報酬改定ダミー	0.010	P<0.01	0.011	P<0.01	0.016	P<0.01
通所介護併設ダミー *介護報酬改定ダミー	-0.010	P<0.01	-0.010	P<0.01	-0.010	P<0.01
月次ダミー						
1 月						
2 月	-0.001	0.07	-0.001	P<0.01	-0.001	P<0.01
3 月	0.000	0.93	0.000	0.56	0.001	P<0.01
4 月	-0.002	P<0.01	-0.003	P<0.01	-0.006	P<0.01
5 月	0.000	0.77	0.000	0.20	-0.004	P<0.01
6 月	0.001	0.06	0.001	P<0.01	-0.002	P<0.01
7 月	0.002	P<0.01	0.002	P<0.01	-0.001	P<0.01
8 月	0.001	0.06	0.001	P<0.01	-0.001	P<0.01
9 月	0.003	P<0.01	0.002	P<0.01	0.001	0.03
10 月	0.004	P<0.01	0.004	P<0.01	0.003	P<0.01
11 月	0.005	P<0.01	0.004	P<0.01	0.003	P<0.01
12 月	0.003	P<0.01	0.003	P<0.01	0.002	P<0.01
cons	-0.135	P<0.01	-0.135	P<0.01	0.575	P<0.01
N. of obsrvations	8800224		8800224		8800224	

* Breusch and Pagan 検定: P value<0.01

* Hausman 検定: $\chi^2(16)=1758.91$: P value<0.01

Table 4　1 か月当たりの通所介護利用日数に与える影響; Second-part（linear model）

	pooling model		random effect model		fixed effect model	
	coef.	P value	coef.	P value	coef.	P value
性別 (1=女性)	0.656	P<0.01	0.640	P<0.01	omitted	
年齢	0.027	P<0.01	0.021	P<0.01	-0.006	0.07
介護度						
要介護 1						
要介護 2	0.627	P<0.01	0.454	P<0.01	0.441	P<0.01
要介護 3	1.901	P<0.01	0.936	P<0.01	0.891	P<0.01
通所介護併設ダミー	0.245	P<0.01	0.229	P<0.01	omitted	
介護報酬改定ダミー	0.435	P<0.01	0.490	P<0.01	0.519	P<0.01
通所介護併設ダミー *介護報酬改定ダミー	-0.043	P<0.01	-0.040	P<0.01	-0.039	P<0.01
月次ダミー						
1 月						
2 月	0.106	P<0.01	0.111	P<0.01	0.115	P<0.01
3 月	0.967	P<0.01	0.978	P<0.01	0.984	P<0.01
4 月	0.187	P<0.01	0.147	P<0.01	0.125	P<0.01
5 月	0.584	P<0.01	0.548	P<0.01	0.528	P<0.01
6 月	0.610	P<0.01	0.579	P<0.01	0.561	P<0.01
7 月	0.715	P<0.01	0.687	P<0.01	0.671	P<0.01
8 月	0.892	P<0.01	0.869	P<0.01	0.855	P<0.01
9 月	0.483	P<0.01	0.465	P<0.01	0.454	P<0.01
10 月	1.006	P<0.01	0.992	P<0.01	0.984	P<0.01
11 月	0.694	P<0.01	0.685	P<0.01	0.678	P<0.01
12 月	0.511	P<0.01	0.506	P<0.01	0.503	P<0.01
cons	6.626	P<0.01	7.387	P<0.01	10.334	P<0.01
N. of obsrvations	4253928		4253928		4253928	

* Breusch and Pagan 検定: P value<0.01

* Hausman 検定: $\chi^2(16)$= 1261.46: P value<0.01

Table 5　1 日当たりの通所介護単位数（基本サービス部分）に与える影響;Third-part（linear model）

	pooling model		random effect model		fixed effect model	
	coef.	P value	coef.	P value	coef.	P value
性別 (1=女性)	13.949	P<0.01	14.415	P<0.01	omitted	
年齢	0.879	P<0.01	0.724	P<0.01	-0.080	0.22
介護度						
要介護 1						
要介護 2	112.021	P<0.01	112.096	P<0.01	112.048	P<0.01
要介護 3	237.746	P<0.01	232.764	P<0.01	232.485	P<0.01
通所介護併設ダミー	-4.226	P<0.01	-4.221	P<0.01	omitted	
介護報酬改定ダミー	-1.972	P<0.01	-1.583	P<0.01	-0.764	P<0.01
通所介護併設ダミー *介護報酬改定ダミー	-0.504	0.01	-0.492	P<0.01	-0.492	P<0.01
月次ダミー						
1 月						
2 月	0.462	0.03	0.505	P<0.01	0.606	P<0.01
3 月	0.855	P<0.01	0.935	P<0.01	1.092	P<0.01
4 月	-0.979	P<0.01	-1.260	P<0.01	-1.866	P<0.01
5 月	0.074	0.73	-0.181	0.05	-0.736	P<0.01
6 月	0.417	0.05	0.190	0.04	-0.308	P<0.01
7 月	1.044	P<0.01	0.843	P<0.01	0.405	P<0.01
8 月	1.144	P<0.01	0.975	P<0.01	0.601	P<0.01
9 月	0.885	P<0.01	0.748	P<0.01	0.441	P<0.01
10 月	1.357	P<0.01	1.253	P<0.01	1.013	P<0.01
11 月	1.296	P<0.01	1.221	P<0.01	1.036	P<0.01
12 月	0.403	0.06	0.367	P<0.01	0.284	P<0.01
cons	582.657	P<0.01	596.178	P<0.01	670.904	P<0.01
N. of obsrvations	4253928		4253928		4253928	

* Breusch and Pagan 検定: P value<0.01

* Hausman 検定: $\chi^2(16)$= 321.97: P value<0.01

Table 6　1 日当たりの通所介護単位数（加算部分）に与える影響;Third-part（linear model）

	pooling model		random effect model		fixed effect model	
	coef.	P value	coef.	P value	coef.	P value
性別 (1=女性)	-2.682	P<0.01	-2.843	P<0.01	omitted	
年齢	0.056	P<0.01	0.053	P<0.01	0.007	0.79
介護度						
要介護 1						
要介護 2	3.641	P<0.01	1.057	P<0.01	0.857	P<0.01
要介護 3	4.815	P<0.01	1.640	P<0.01	1.339	P<0.01
通所介護併設ダミー	3.601	P<0.01	3.522	P<0.01	omitted	
介護報酬改定ダミー	10.067	P<0.01	10.261	P<0.01	10.325	P<0.01
通所介護併設ダミー *介護報酬改定ダミー	-0.340	P<0.01	-0.323	P<0.01	-0.321	P<0.01
月次ダミー						
1 月						
2 月	0.070	0.36	0.087	0.02	0.095	0.02
3 月	0.023	0.77	0.059	0.13	0.071	0.07
4 月	-1.880	P<0.01	-2.033	P<0.01	-2.081	P<0.01
5 月	-0.998	P<0.01	-1.133	P<0.01	-1.176	P<0.01
6 月	-0.315	P<0.01	-0.433	P<0.01	-0.471	P<0.01
7 月	0.147	0.06	0.044	0.26	0.010	0.81
8 月	0.284	P<0.01	0.202	P<0.01	0.173	P<0.01
9 月	0.314	P<0.01	0.249	P<0.01	0.226	P<0.01
10 月	0.079	0.30	0.033	0.39	0.016	0.69
11 月	-0.039	0.62	-0.068	0.08	-0.081	0.04
12 月	-0.066	0.39	-0.081	0.04	-0.087	0.03
cons	55.098	P<0.01	55.098	P<0.01	61.635	P<0.01
N. of obsrvations	4253928		4253928		4253928	

* Breusch and Pagan 検定: P value<0.01

* Hausman 検定: $\chi^2(16)$= 567.99: P value<0.01

Table 7　1 か月当たりの居宅サービス単位数に与える影響

	pooling model		randam effect model		fixed effect model	
	coef.	P value	coef.	P value	coef.	P value
性別 (1=女性)	353.5	P<0.01	330.1	P<0.01	omitted	
年齢	74.6	P<0.01	58.8	P<0.01	-2.4	0.3
介護度						
要介護 1						
要介護 2	2176.5	P<0.01	1767.1	P<0.01	1744.9	P<0.01
要介護 3	6210.0	P<0.01	4196.8	P<0.01	4124.3	P<0.01
通所介護併設ダミー	688.1	P<0.01	665.5	P<0.01	omitted	
介護報酬改定ダミー	520.9	P<0.01	626.5	P<0.01	691.0	P<0.01
通所介護併設ダミー 　*介護報酬改定ダミー	124.9	P<0.01	136.0	P<0.01	136.4	P<0.01
月次ダミー						
1 月						
2 月	76.0	P<0.01	87.4	P<0.01	95.2	P<0.01
3 月	763.0	P<0.01	785.6	P<0.01	798.0	P<0.01
4 月	-53.7	P<0.01	-132.2	P<0.01	-179.9	P<0.01
5 月	255.7	P<0.01	185.8	P<0.01	142.2	P<0.01
6 月	324.0	P<0.01	262.2	P<0.01	223.1	P<0.01
7 月	419.4	P<0.01	364.5	P<0.01	330.1	P<0.01
8 月	602.5	P<0.01	556.7	P<0.01	527.4	P<0.01
9 月	274.9	P<0.01	237.7	P<0.01	213.7	P<0.01
10 月	702.9	P<0.01	675.1	P<0.01	656.3	P<0.01
11 月	489.8	P<0.01	470.6	P<0.01	456.3	P<0.01
12 月	358.2	P<0.01	348.7	P<0.01	342.3	P<0.01
cons	-825.6	P<0.01	1079.8	P<0.01	6827.2	P<0.01
N. of obsrvations	4253928		4253928		4253928	

* Breusch and Pagan 検定: P value<0.01

* Hausman 検定: $\chi^2(16)$= 9684.77 P value<0.01

添付資料２　Working Paper

Socioeconomic within-gender gap in informal caregiving among middle-aged women: an evidence from Japanese nationwide survey

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1. Introduction

Care giving to older people with needs has been dominantly dependent on informal care provision by female caregivers. A recent meta-analysis of 229 studies reported that 69% of the informal caregivers were women, and that gender gap existed in hours and numbers of care taking [1]. Gender-biased burden of caregiving could be attributed to traditional norms about gender roles [2, 3], gender-specific skills for caring [4], or gender gap in wage in labor market [5].

In order to relieve and equalize the burden of care in the household [3, 6], some countries including Japan have introduced long-term care insurance (LTCI) system to provide formal care services with affordable copayment [2, 7] that at least partially succeeded in increasing labor market participation of women [8]. However, there remains a gap within gender; women in lower income household did not enjoy such benefit.

As we know of, a within-gender gap across socioeconomic status (SES) has been only poorly studied in informal care giving. Most previous studies focusing on gender disparity in informal care provision ignored a gap across caregivers' SES [9, 10, 11, 12, 13, 14, 15, 16, 17]. Gender and socioeconomic status as represented in income, occupation, and educational attainment are conceptually independent [18, 19, 20, 21], but are intertwined in social stratification of life chances

and risks [22]. Women have a larger risk of low income, low educational attainment, and limited opportunities to access resources such as healthcare [23, 24, 25, 26, 27, 28, 29, 30].

Under these backgrounds, women in low socioeconomic status (SES) may face a larger risk of biased care burden because they lacks resources to buy formal care, have less social support, and/or have no choice but remains in household for informal care without labor force skills. Such intertwined impact of gender and SES on the distribution of informal care burden, if exists, deserves policy attention to design welfare program for fair contribution and compensation of informal care in the society. The focus on not only gender gap, but disparity within women is considered important, while we are not aware of any literature directly addressing socioeconomic within-gender gap in informal care giving among women.

The aim of this study was to reveal the association of SES of women with the chance of being a primary caregiver for older people in needs. We focused particularly on household income, marital status, work status, and educational background among women.

2. **Subjects and methods**

2.1. Data source

A public insurance system has been an exclusively dominant platform to provide a formal LTC in Japan since 2000 [2]. The eligibility of formal care service use is based solely on a functional assessment of the recipient through a standardized protocol, regardless of households' demographic and SES conditions, and copayment is reduced or exempted in case of low-income households. We believe the investigation of within-gender gap in informal care provision under public LTC provision in Japan would help us identify a gap attributable to women's status in the household regardless of household's affordability of LTC.

For this study, we utilized data from the Comprehensive Survey of Living Conditions of the People on Health and Welfare (CSLCP), a nationwide representative, population based cross-sectional survey of households that is conducted every three years by the Ministry of Health Labour and Welfare in Japan. We pooled data derived from 2010 and 2013 surveys to obtain a sufficient size for analysis. The 2010 survey used a probabilistic sampling of about 5500 sampling area units stratified by 47 prefectures in Japan, then asked all the households in the sampled unit to participate in the self-administered questionnaire survey on household sociodemographic conditions and health status, educational status, marital status and work status of household members. In 2500 randomly-selected area units from the original sample, an additional questionnaire was further distributed to all households having a member eligible for public LTC at the time of the survey to collect information regarding formal LTC service use, informal care giving, and functional conditions of care recipients.

2.2 Subjects and sampling

For our purpose, we have to define the "population at risk", or those who could be an informal caregiver in the household and/or labor force in formal labor market. To focus on a within-gender gap, we excluded male subjects from our analysis. We further limited our sample to females aged between 40 and 60 because women in this range of age are the most likely to be involved in personal care mainly with their elderly parents, and at the same time, they can be still part of the labor force [11, 31, 32]. We exclude women older than 60, the age of public pension eligibility, because they were more likely retired, and to be involved in care giving of their old spouses/parents regardless of socioeconomic status.

In 2010, the original survey included 228,864 households and 609,018 subjects from 5,510 sampling units in 47 prefectures in Japan (household response rate=79.1%). 7192 households were eligible for LTC survey, of which 5912 households gave effective response. We limited our analysis to 2980 households where care recipients had cohabitation with primary caregivers within the same household. We did so because the survey collected detailed information of care givers only in the same household with the care recipient. We excluded 59 households where the caregiver took care of more than two care recipients at the same time. Consequently, 1103 households and their 1181 women aged 40-60 years of working age were available as target sample for further analysis. We conducted similar procedures for the 2013 data; we appended the datasets to obtain 2399 female subjects in 2236 households.

2.2 Measurement

2.2.1 Female family member characteristics

We considered female family members' characteristics, including age (40=<age<50 or 50=< <60), marital status (whether currently married) [29], health status (whether have a chronic disease under treatment). Job status (full-time job, part-time job, no-job) [33], and educational attainment ("junior or high school degree", "community college or training graduates", and "university or graduates or above") were counted as an indicator of female's individual SES.

2.2.2. Care recipient characteristics

We included care recipients' characteristics such as age, gender, health status and care eligibility level in public LTCI as indicators of the amount of care required. More specifically, eligibility level higher than II indicated those without functional independence, and need assistance in meal, toileting, bathing, and clothing [2, 3]. We divided the level into severe (Level III, IV, and V) vs. mild (Level I and II, and less than Level I).

2.2.3. Household characteristics

The number of household members over 18 years aged living together was included in the analysis because it should reflect the household capacity for informal care provision and the need for formal care related to household structure. The existence of the household members under 18 years old was also included because it should reflect conflicting demand for care provision to dependent children in the household. Equivalent household income was obtained through imputation, of which details are available elsewhere [3].

2.3. Statistical analysis

We compared caregiver women and non-caregiver ones in their demographic, socioeconomic, and health statuses by using t-tests and chi-square tests as they fit. We also compared by the caregiving status of women the characteristics of cohabited care recipients and their households. Then, we conducted multiple logistic regressions of caregiving status as a target variable, regressed on women's socioeconomic status with adjustment for care recipient's and household characteristics (e.g., care level, gender, and chronic disease under treatment, household composition, and equivalent household income). Since the severity of care need may differentially affect the chance of being caregivers, we tested interaction terms between care eligibility level of the care recipient and caregiver's educational, job status, and marital status. As we found a significant interaction by education and marital status, analysis stratified by care eligibility level (mild and severe) was additionally conducted. Statistical significant was inferred at a p value of 0.05. The results from the multivariate analysis were expressed as odds ratio (OR) with 95% confidence intervals (CI).

4. Results

The characteristics of female members (non-caregivers, caregivers), care recipients, and households by caregiving status are presented in Table 1. All of the 982 non-caregiver women were cohabited with caregiver family members, majority of whom were women older than 60 or younger than 40 (not shown in the table). Caregiver women were on an average 3 years older than non-caregiver counterparts (p=<.0001) and more likely to have chronic conditions (p=<0.0001). Caregiver women were more likely to have high-school education or less, and to be non-workers, as well. Finally, caregiver women were more likely to be cohabited with care recipients of older age, female gender, and mild care needs. Finally, a quarter of caregiver women belonged to the lowest quartile group of household income.

Table2 showed the results of multivariate logistic regression analysis for caregiving status as an outcome. Younger age, fulltime work status, and married status were significantly related to non-caregiving status, while education was not significantly related to the caregiving status (model 1). However, after including an interaction term between education and care recipient's care levels, the interaction was significant (loglikelihood ratio test p=0.0003), and high school education or less turned to be significantly related to the chance of being a caregiver (p=0.0001). Marital status also showed a significant interaction with the care eligibility levels (loglikelihood ratio test p=0.0015, not shown in the table).

Table3 shows the results of adhoc analysis stratified by care recipient's care eligibility level. the odds ratio of the possibility of primary caregiver by subgroup, the caregiver living with care recipient at mild level and at severe level, respectively. It is found that compared with the caregivers (n=693 of 1074)) with care recipient at mild care level and those at severe level (n=725 of 1325) were significantly associated with the elder age-group (OR, 0.61; 95% CI, 0.43-0.86 vs. OR,0.41; 95%CI,0.29-0.56), full time job (OR,0.46; 95%CI,0.28-0.76 vs. OR,0.36; 95%CI,0.23-0.55) , married (OR,1.02; 95%CI,0.65-1.60 vs. OR,0.41 ;95%CI,0.27-0.64) and lower level education (OR,1.00; 95%CI, 0.67-1.49 vs. OR,1.94; 95%CI,1.37-2.74).

5. Discussion

LTCI was introduced in order to relieve the burden of the caregivers and equalize it in 2000. Nevertheless, much more women still remain informal caregiver than men. To the best of our knowledge, this study is the first to investigate that the inequality within women for primary caregiver might be caused not only by the gender gap, but by the socioeconomic gap, using the nationwide representative population based data.

Our results showed that there was no significant association between educational or marital status and caregiver living with care recipient after adjustment for equivalent household income, demographic variables of care recipient. But, in the subgroup analysis by care recipient's stratum of severity, the women with lower human resources were likely to be caregiver with care recipient at severe level: the women with lower educational background, non-marital status, older, and unemployed, while the women living with care recipient at mild level were not associated with educational status or marital status significantly.

For the cause of this observed linkage, there are two possible explanations. First, the severe care level accounts for a lot of demand for care provided. For care recipient with mild care level which caregiver may provide more casual help, even caregiver in full-time will be easy to care. But, for care recipient with severe care level who needs to be watched for almost all day, caregiver in

full-time work may be difficult to care and have to buy more care services or quit her work or change her job into lower-paying jobs that accommodate part-time hours or flexible schedules to make time for care [34]. As a result, as the more severe the care level of the care-recipient, the more likely the caregiver will have to take a leave of absence from their job in order to provide care.

Second, for the more severe recipient, it takes longer time to care and more cost. Under such occasion, women with higher human capital may have a strong tendency to go out for their work instead of caring by themselves because of their own high opportunity cost. On the contrary, women with lower human capital have to stay at home for caring, because they may have little financial gain from going out to work even if they seek a job; Educational level is a major determinant of the value of time. The shadow price of time of college graduates exceeds that of high school graduates or below [35]. The problem of wage gap was caused not only between men and women, but even within women.

LTC is closely connected with shadow price because the informal care is low-value-added and cheaper labor than other labors. Consequently, socially- and economically-vulnerable people, such as women with disadvantage who are unmarried, unemployed or with lower education, tend to be inflicted caregivers by other family members. Policy makers should more discuss about double burden, socio-economic and gender inequality, upon female caregivers who are not financially independent. We made a suggestion that we should add more value to informal care by cash benefit in order to compensate the gap between caregiver and non-caregiver or design some housing with flexible assistance to meet the caregiver's needs, especially in severe case[36].

While our strengths of our study are based on a large national population-based with high coverage data, we could not take into account for several limitations. First, this was cross-sectional data, so that we could not distinguish which comes first, woman with no job might be stuck with care by other family members or as a reverse direction of causality, woman might resign her job after she became caregiver. Further research with panel data should be needed. Second, we understood that relationship between caregiver and care recipient such as daughters-in-law and married daughter have played an important role in informal care-giving arrangements within East Asian traditional norms[37] [38][39]. But, we could not put their relationship as variable, because we could not distinguish whether it was biological or marital relationship because of data availability.

6. Conclusion

LTCI was introduced in Japan to lighten the traditional gender-biased burden of caregivers. Recently, the gender-biased burden has been lightened. On the other hand, our study indicated that there still remained the problem of within gender discrimination influenced by human

capital such as marital status, labor status, and educational status for the possibility of the caregiver among women aged 40-60 living with care-recipient. To equalize the gap between caregivers and non-caregivers under LTC, policy makers should design the respite care services for 24 hours in order to relieve their burden, or revise LTCI systems involving the cash benefit.

Conflict of interest

The authors have no conflicts of interest to declare.

Ethics approval/Statement

Anonymous secondary data are approved for research use by the governmental agency, and ethical consideration is waived.

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添付資料２

Development of micro-simulation model to forecast health and wellbeing in older Japanese

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Abstract
Rapid population aging is regarded as a risk to social sustainability of Japan. Precise estimation of future demand for medical and long-term care in heterogeneous segments of older people is imperative for designing system reform and stability. Currently available future projection, however, simply assumes static and average status of comorbid prevalence and mortality by age and sex. To overcome the limitation, a state-transition multivariable micro-simulation model was developed by following previously developed US Future Elderly Model (FEM), but using Japanese national representative panel data as benchmark reference. Preliminary comparison between estimation and real-world vital statistics confirmed backward validity of our simulation forecast, except for overestimation of cancer death numbers. We discuss potential improvement of the model, and future application of the developed model for policy evaluation.

1. Background

Rapid population aging is regarded as a risk to social sustainability of Japan (Cabinet Office, 2015). Increasing demand for pension support, and medical / long-term care against decreasing support resources threats financial projection of the nation's economy. Population ageing also leads to a considerable disparity among older people in terms of their economic, health, and social resources (Ichimura, et al. 2009). Apparently, precise estimation of future demand for health and social services in heterogeneous segments of older people is imperative to design efficient system reform and stability.

Further challenge to future projection of people's health is that health affects and is affected by socioeconomic conditions (WHO, 2008), and change in life conditions and available health technologies over time leads to change in people's likelihood of health, function, comorbidity and death (Tango, and Kurashina, 1987; Ma, et al. 2007; Wang, et al. 2015). Currently available future projection, however, simply assumes static and average status of comorbid prevalence and mortality by age and sex strata (National Institute of Population and Social Security Research, 2012), fails to incorporate diverse and dynamic associations between health, economy, and social conditions among older people.

One countermeasure to overcome the limitation above has been proposed by Goldman and his colleague economists. Future Elderly Model (FEM) incorporates comprehensive measurement derived from panel data surveys to produce micro-simulation of older people's health, function, mortality, social participation, and economy (Goldman, et al. 2004: Lakdawalla, 2014). The model has been applied to a wide range of policy projection in public health, (Goldman, et al. 2009; Lakdawalla, et al. 2005; Lakdawalla, and Philipson, 2009; Michaud, et al. 2012), healthcare (Bhattacharya, et al. 2005; Lakdawalla, et al. 2009), technology innovation

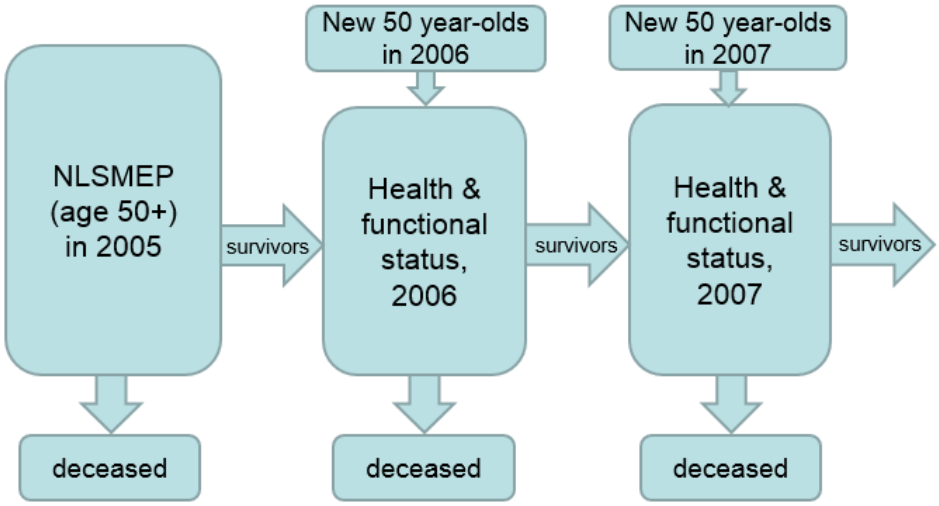
impact (Goldman, et al. 2005), and public finance (Michaud, et al. 2011). Most recently, the model was applied to older population in European and other countries including Japan (Chen, et al. 2016). However, the model development in Japanese context is still in its early stage, and reference data use is limited to a few data source available to US researchers.

In this paper, we report our interim results of developing a version of Japanese FEM with the use of wider set of nationally representative micro data sources to complement previous trials. Our aim to apply nationally representative data source is two folds; to better reflect Japanese demographic and vital status in the projection, and to improve estimation precision to reflect Japanese population in older age.

2. What is FEM

FEM is a Markovian-based multivariate micro-simulation model that consists of three components: health transition module, mortality module, and new cohort module (Figure 1). Health transition module comprises of the probability matrix that reflects disease incidence and transition of individual's multiple comorbidity statuses (horizontal arrows in Fig 1). Mortality module, vertical arrows in Figure1, contains the probability of mortality exit from survivors by accounting for individual's comorbidity status in a previous time period. New cohort module generates a new cohort to newly enter elderly population aged 50 years old and over.

Figure1. Framework of FEM



3. Estimation methods and data sources

3-1. Health transition module

In FEM, the probability of disease incidence is generated by first-order Markov process.

Let H_t denotes a vector of individual's health status at time *t*, and X denotes a vector of demographic characteristics such as birth year, educational status, marital status, and smoking habit in the initial survey year (see Appendix Table1 for included variables). We assumed the probability of disease incidence at the subsequent period H_{t+1}^* follows logistic distribution: for any individual,

$$H^*_{t+1} = H(H_t, X). \quad (1)$$

We defined the individual's health status with comorbid conditions of 6 statuses (heart disease, hypertension, hyperlipidemia, stroke, diabetes, and cancer of any kind) since these conditions are major causes of death and underlying risk factors (Ikeda, et al. 2011). We assumed all health conditions are absorbing states (or once diagnosed, the condition continues until death or attrition):

$$H_{t+1} = \max(\, I(H^*_{t+1} > 0),\ H_t) \quad (2)$$

where I(.) denotes an index function.

To calculate the health transition probabilities, we estimated a random effect logit model separately for each chronic condition. To rewrite equation (1) as

$$H^*_{i,t+1} = \beta'(X_i, a_{i,t}) + \gamma' H_{i,t} + \eta_i + \varepsilon_{i,t} \quad (3)$$

for each individual *i* aged $a_{i,t}$ at time *t*.

We measured demographic characteristics X with gender, educational status, marital status, and smoking habit in the initial survey year. We defined time variant health status with comorbid conditions provided by 6 dichotomous variables. η_i and $\varepsilon_{i,t}$ are unobserved heterogeneity and the error term, respectively. Coefficients β and γ in equation (3) provide transition matrix for calculation of disease incidence.

We excluded individuals who were already diagnosed in the first wave of panel data for each condition to purify transition probability of disease incidence, rather than prevalence.

3-2. Mortality module

In mortality module, we included in the module the probabilities of death from heart disease, cancer, and stroke since they are the 3 main causes of death in Japan. Approximately 65% of deaths among 50s, 60s and 70s population are attributable to these 3 diseases (Health, Labour and Welfare Statistics Association, 2015). Although the original FEM contains more than 10 causes of death, we believe starting with a mortality module with 3 main causes provides a step board for a more extended module. We regarded heart disease (I01-I02.0, I05-I09, I20-I25, I27, I30-I52), cancer (C00-C97), and stroke (I60-I69) coded in International Classification of Death cause version10 (ICD-10).

To build this module, we need to treat competing risks among death causes. For example, an individual with diagnosed conditions of heart disease and stroke in time period t may die of heart disease, stroke, combination of both causes, or other causes of death in the following time period (Figure 2-a). We need to specify competing attribution of death causes to a subpopulation with a certain set of chronic comorbidity conditions.

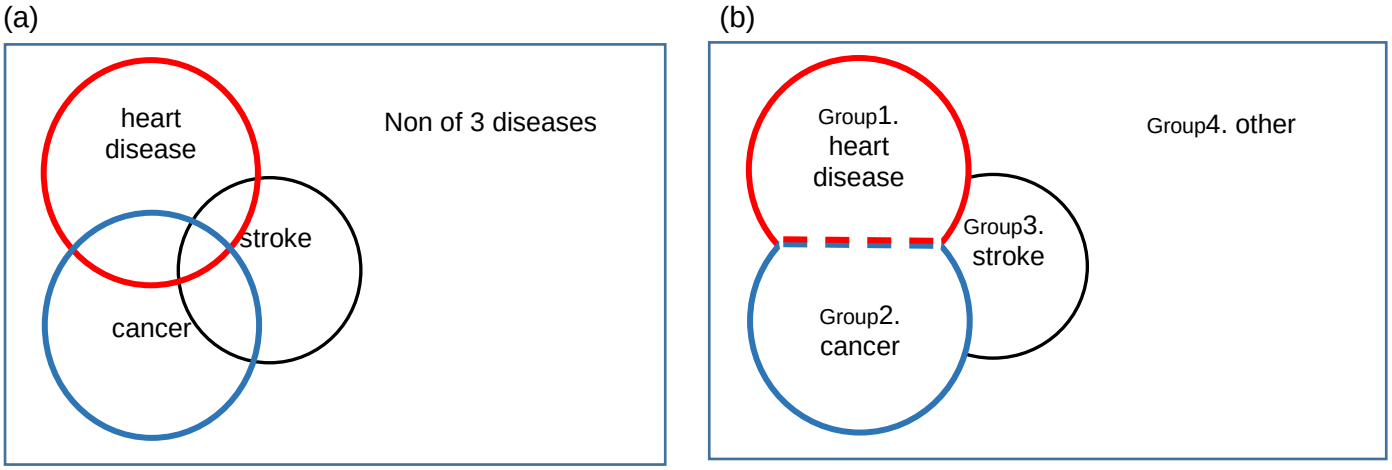
Ideally, vital statistics with multiple causes of death linked with cohort observation of past comorbidity status is the best resource to obtain such multiple attribution of comorbidity and death causes. In reality, such data is very difficult to obtain. Instead, for model simplicity, the original FEM assumes that comorbidity corresponds to a cause of death (e.g. an individual with heart disease will die of heart disease), and that

multiple comorbidity leads to additive probability of mortality from corresponding comorbidity statuses (e.g. mortality of heart disease + mortality of cancer for a case with the two comorbidity statuses).

Since this will lead to upwardly biased mortality, we assumed instead in our model that causes of death are grouped in mutually exclusive manner (Figure 2-b), and each category has a priority cause of death (Table1).

In more details, if comorbidity of heart disease and stroke occurs, we prioritize death from heart disease because heart disease survivors are most likely to die of heart disease, while even stroke survivors would have a 22% chance to die of heart conditions (Bronnum, et al. 2001). We prioritized cancer death when comorbidity of cancer and stroke occurs because cancer patients are most likely to die of cancer, and about 12% of stroke survivors also die of cancer. If comorbidity of heart disease and cancer occurs, we differentially assign death cause according to the time order of comorbidity incidence. We assign death of heart disease in the case that individual was diagnosed with heart disease earlier than with cancer, and vice versa.

Figure2. Venn diagram of disease comorbidity (left) and disjoint groups for assignment to one cause specific mortality (right)



Note: Exterior rectangle (universal set) illustrates the total population. (a) Red, blue, black circles denote groups of patients with heart disease, cancer, and stroke. Comorbidity status is represented intersection of circles. Patients in the intersection of red and blue circles are diagnosed with heart disease and cancer. If people who haven't been diagnosed any of three diseases, they will be located out of circles. (b) To assign a priority cause of death, patients who suffer from multiple diseases will be categorized in one group out of three under mutually exclusive rule in Table1. People who suffer from none of 3 diseases will belong to the fourth group.

Table1. Classification of 4 groups

Group (likely to die from…)	Health condition in the previous year
1. Heart disease	Heart Heart+Stroke

	Heart(earlier incidence)+Cancer Heart(earlier incidence)+Cancer+Stroke
2. Cancer	Cancer Cancer+Stroke Cancer(earlier incidence or coincidence)+Heart Cancer(earlier incidence or coincidence)+Heart+Stroke
3. Stroke	Stroke
4. Other	None of Heart, Cancer, or Stroke

Finally, sex specific mortality rate for age strata by 1 year was obtained as follows. First, we calculated the estimated number of individuals with a set of comorbidity by direct standardization method, using 2005 Census population as a reference population, and the proportion of the corresponding set of comorbidity obtained from social survey datasets we adopted of which details are presented shortly. Then, we obtained the number of mortality case due of culprit causes of death from vital statistic records, following the assumed rules shown in Table 1. Obtained number of cases was divided by the number of individuals with corresponding set of comorbidity to make disease specific mortality rate for each age-sex strata.

3-3. Backward validity check

Using health transition and mortality modules as developed above, we estimated a trend of comorbidity prevalence and cause specific mortality of a virtual closed cohort over a period of time, and compared the estimation results with observed statistics of corresponding age-sex strata in referred survey data for backward validity check of the estimation precision.

Consequently, in this report, we did not treat new cohort module in our simulation, because new cohort module is necessary only in the case of open-cohort assumption that is required for future population projection.[1]

3-4. Data sources

To obtain transition probability of statuses, panel data structure is the most preferred source for the purpose. The Original FEM relied mainly on a nationally representative panel dataset such as The Health and Retirement Study (HRS) and Medicare Beneficiary Survey (MCBS), and complementally used a nationally representative cross-sectional data such as National Health Interview Surveys (NHIS). For mortality modules, they relied on vital statistics records linked with HRS (Goldman, et al. 2009; Lakdawalla, et al. 2009).

Contrarily, Chen et al. (2016) developed a demographic, health and economic state-transition micro-simulation model for Japan adopting the Future Elderly Model (EFM) to forecast trend in disability among Japanese elderly using Japan Study of Aging and Retirement (JSTAR) and Nihon University

[1] New cohort module generates incoming cohort for the subsequent time period. US FEM integrated the joint distribution of demographic and health status of initial 50 year-old population from HRS and health trends among under 50 years old population from NHIS (Goldman, et al. 2004).

Japanese Longitudinal Study of Aging (NUJLSOA). NUJLSOA adopted a probabilistic sample of Japanese aged over 65, while JSTAR adopted probabilistic sample of those aged 50-75 at the baseline in selective municipalities across the nation, and does not provide nationally representative figures.

In this paper, we focused on health transition module and mortality module. We used 8 waves of National Longitudinal Survey of Middle-aged and Elderly People (NLSMEP) and 3 waves of Japanese Study of Ageing and Retirement (JSTAR) for estimation of the probability of disease incidence. We also used a microdata of vital statistics between the period of 2005 and 2012 for estimation of the probability of disease specific mortality. Details of data sources are described in the appendix.

4. Estimation results

4-1. Health transition module

From parameter estimates fitting random effect logit model based on NLSMEP, we obtained the transition matrix A (Table 2). As NLSMEP is annual panel data, the transition matrix A reflects transition of health conditions with 1-year interval.

Random effect assumption was supported by the high values of rho (second row from the bottom in Table2). Age was associated with increased risk of incidence for all diseases. The incidence of heart disease was significantly associated with diabetes, hypertension, and hyperlipidemia that is on par with existing epidemiological evidence. Stroke was also associated with heart disease, but this seems more likely due to their common risk factors.

Incidence of cancer showed associations with all other chronic conditions, which is not well explained by biological mechanism. We interpreted this as a residual confounding by age rather than reflecting underlying biological causes of cancer. Significant prediction of diabetes by preceding heart disease condition may also need careful treatment because it would be rather due to a reverse causation. As such, the estimated probability matrix does not necessarily fit biomedical associations among comorbidity conditions, which is already known in US FEM (Lakdawalla, 2014). Because of this, theoretical adjustment of estimated transition matrix is recommended based on existing medical and epidemiological evidences.

Parameter estimates from JSTAR provided the transition matrix B (Table 3). The transition matrix B transits health conditions with 2-year interval because JSTAR is a 2 year cycled panel data. Matrix B gives us similar patterns as in matrix A.

Table2. Paneled logit estimators for calculation of the probability of disease incidence based on NLSMEP (transition matrix A)

	Diabetes	Heart	Stroke	Hypertension	Hyperlipidemia	Cancer
Male	2.336	1.324	0.586	1.205	-1.582	-0.281
Education	-1.114	0.599	-1.259	0.165	1.699	0.028
Marital	-0.926	-1.268	-0.326	0.125	-1.180	-0.199
Smoke	0.924	1.212	1.027	0.840	0.043	0.616

Age	1.539	0.837	0.699	1.593	1.685	1.025
Diabetes		1.855	1.549	1.487	0.975	0.707
Heart	1.625		2.577	1.654	1.020	0.490
Stroke	0.816	2.453		3.085	0.434	0.739
Hypertension	1.765	2.830	3.679		2.010	0.276
Hyperlipidemia	1.737	1.365	0.986	1.663		0.670
Cancer	0.752	0.783	1.452	-0.087	0.649	
Constant	-112.448	-66.704	-62.039	-107.612	-117.213	-78.274
sigma_u	13.493	8.666	8.635	13.069	18.222	9.622
Rho	0.982	0.958	0.958	0.981	0.990	0.966
Log-likelihood	-13324.4	-10459.7	-6109.4	-24180.2	-24657.4	-9518.4

Note: Sigma_u denotes the standard deviation of the panel-level variance component. Rho measures contribution of the panel-level variance component out of the total variance.

Table3. Paneled logit estimators for calculation of the probability of disease incidence based on JSTAR (transition matrix B)

	Diabetes	Heart	Stroke	Hypertension	hyperlipidemia	Cancer
Male	1.714	1.115	2.653	0.942	-0.769	1.524
Education	-0.732	0.467	-0.591	-0.363	0.571	0.038
Marital	-0.003	0.734	2.242	0.026	0.445	0.837
Smoke	-0.239	-0.421	-0.186	-0.117	-0.523	0.290
Age	0.005	0.164	0.342	0.150	0.021	0.167
Diabetes		0.797	1.340	0.166	0.833	0.387
Heart	0.021		0.526	0.388	-0.318	-1.104
Stroke	1.217	0.289		1.434	0.247	-0.512
Hypertension	1.572	0.762	2.052		0.655	0.297
Hyperlipidemia	1.704	0.962	0.991	1.348		-1.839
Cancer	1.475	-0.149	1.562	-0.235	-0.381	
Constant	-16.455	-24.689	-43.054	-17.193	-8.368	-26.087
sigma_u	7.660	6.168	6.791	5.591	3.668	5.957
Rho	0.947	0.920	0.933	0.905	0.804	0.915
Log-likelihood	-576.2	-539.5	-346.3	-1,194.9	-865.4	-371.2

4-2. Mortality module

We plotted the probabilities of death from heart disease, cancer, stroke, and other causes in Figures 3 and 4. Both NLSMEP and JSTAR suggest the probability of cancer death is much higher than heart disease and stroke for both male and female.

Mortality rate of cancer for male in Figure 3 jumped at 51 years old that seems effect of underdiagnoses in the first wave of NLSMEP. Similar effects can be observed in all 3 diseases for both male and female. Moreover, because very small number of middle aged females experienced stroke, disease specific mortality rate of stroke for females aged 50s looked unstable relative to others. Overall, the mortality rate attributable to heart disease, stroke, and cancer gradually decreased among NLSMEP population for both male and female while Japanese official death rates by cause of death (per 100,000 population) increases among 50s and 60s population (Vital Statistics 2014). We concluded that our disease specific mortality rates

are considerably affected by underdiagnosis of preceding comorbidity conditions.

We extended curves of disease specific mortality rate up to 77 years old using JSTAR. We observed the mortality rate attributable to heart disease, stroke, and cancer increases for both male and female which is consistent with official death rate of Japan.

Fugure3. Disease specific mortality rate based on NLSMEP and vital statistics (50 - 66 years old)

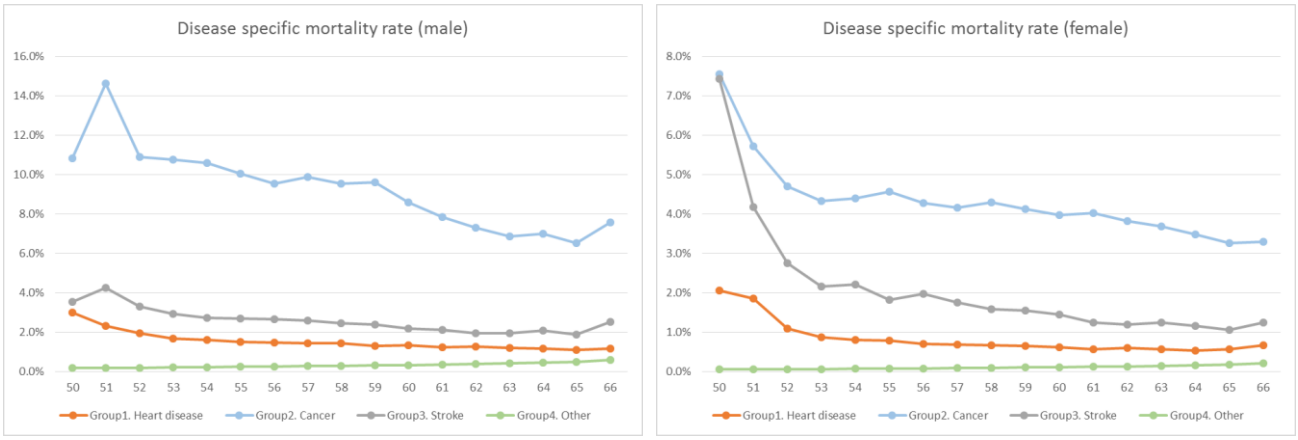
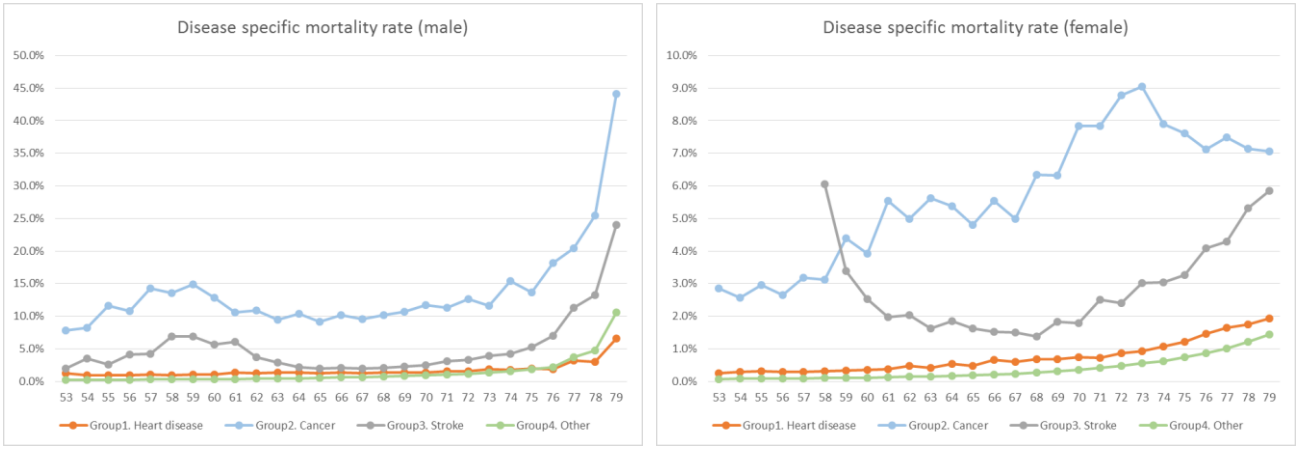


Figure4. Disease specific mortality rate based on JSTAR and vital statistics



4-3. Backward validation check

We assessed our simulation result with backward validation. We started our simulation from year 2005 to compare the results with observed numbers in NLSMEP. First, we executed random sampling by age and gender from 1st wave of NLSMEP with replacement, in order to replicate Japanese population in 2005 between 50 years old and 59 years old, keeping information of age, gender, education, marital status, smoking history, health conditions (heart disease, hypertension, hyperlipidemia, stroke, diabetes, and cancer). Second, 6 health conditions were transited in the individual level from year 2005 to year 2006 by transition module. Third, we categorized individuals into 4 groups by classification in Table 3, and then we assigned them corresponding disease specific mortality rates. At last, probabilistic mortality exists happened

in 2005 population, and then we obtained 2006 population. We repeated the same steps for year 2006 through 2012 (Figure 5).

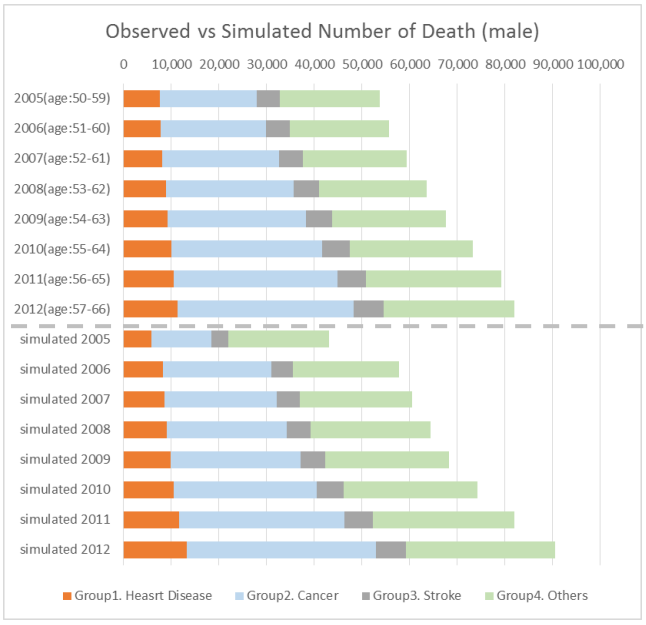
Next, we extended the range of age of our simulation using JSTAR. As JSTAR survey started in 2007, we set the initial population as with 2007 Japanese population. Because the sample size in JSTAR is not sufficiently large, we pooled all 3 waves of JSTAR and took 3 consecutive observations by birth cohort groups. For instance, when we created 53 year old population of 2007 for our simulation, we randomly sampled from observations of 52 years old, 53 years old, and 54 years old in the 1st, 2nd, and 3rd waves. We transited health conditions in 2-year cycle, and we executed mortality module twice before we ran the next transition module.

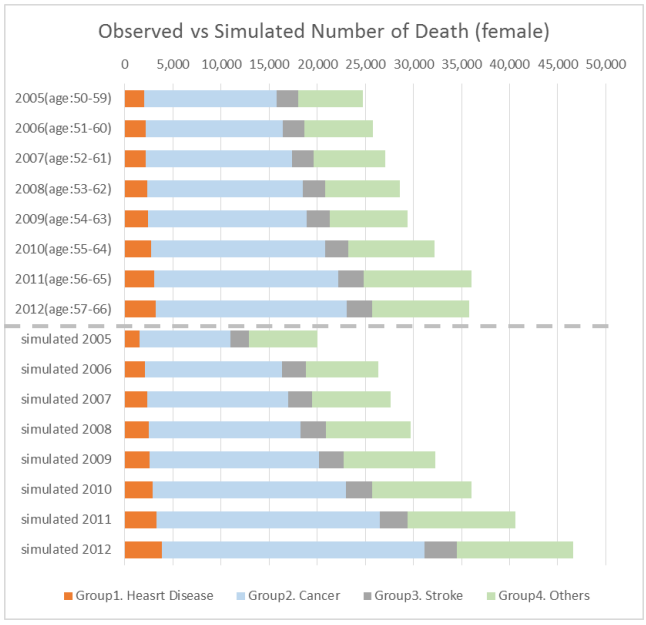
Figures 5 and 6 describe the simulation results based on NLSMEP and vital statistics. Exact numbers in the figures are listed in Appendix Tables 3-6. Our model underestimated the number of mortality in 2005 for both male and female, probably, due to underdiagnosis of comorbidity conditions in the first wave of the panel data. Splitting the results by age (not shown), our model seemed to fit well for the 53-56 age group, however, it underestimated the diseased population for 50-52 age group and overestimated the diseased population for 57-59 age group. The number of cancer deaths in 2012 was overestimated and it was particularly notable for 57-59 age group. JSTAR suggested similar results.

Overestimation of cancer deaths happened partly because our transition matrices may suffer from reverse causal links and confounding bias as we mentioned earlier. Our simulation may need further refinement of matrix elements to better fit biomedical/epidemiological evidence on comorbidity conditions and death causes.

Figure 5. Estimated population from NLSMEP (upper) vs simulated population (lower)

Figure 6. Observed number of death in Vital Statistics (upper) and simulated number of death (lower)





5. Discussion for future study

As our interim results showed, the projection of comorbidity prevalence and cause-specific mortality through developed simulation fairly follows a real-world trend of older people's health status, though it still needs rigorous refinement, especially in mortality module.

In addition to model refinement, extension of coverage over older population is a challenge. NLSMEP and JSTAR do not cover those aged 75 and over, and currently we could not identify suitable panel data source for older age strata. A possible alternative is to use repeated cross-sectional data of national representative survey as pseudo-panel data. For this purpose, National Comprehensive Survey of Living Conditions of People on Health and Welfare (NCSLCPHW), conducted every three years and most latest in 2013, would be suitable.

There are several morbidity and functional conditions that we have failed to include in the module at this stage partly because (i) ADL limitation rarely happens to NLSMEP population (aged 50-66 years old) and (ii) NLSMEP lacks main causal diseases of ADL limitation (e.g. osteo-arthritis, cognitive disease, and so on) except stroke. Since we obtained better projection when we dropped ADL limitation from estimators of transition probabilities, we thought ADL limitation was noise rather than predictor of comorbidity conditions for NLSMEP population for the reason above. However, there might exist other solutions to improve our model (e.g. to exclude reverse causal relationships from the health transition matrix). In the next step, we will attempt to incorporate ADL difficulty, IADL difficulty, and additional health conditions (e.g. dementia, arthritis) from JSTAR. To improve prediction of functional status, we plan to involve socioeconomic status (e.g. currently work or not) as well.

Involving socioeconomic status into the dynamic model will enable us to see complex effects across health and economic outcomes (Shimizutani, et al. 2014; Stowasser, et al. 2011). FEM may be a powerful tool for visualizing wealth-health gradient among population. A challenge will be how to obtain stable estimation with reduced sample size after stratification by socioeconomic status. Bayesian estimation and smoothing

methods would be necessary to be included in the model building.

Despite of these expected challenges, development of Japanese FEM would be a promising endeavor to open new methods of policy evaluation and experimental policy discussion and to deepen our understanding on complex and dynamic health-wellbeing associations among diverse older people in this country.

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We are grateful to Professor Jay Bhattacharya at Stanford University for his helpful advice and the data usage of JSTAR (Name of Research: A Future Elderly Model for Japan: Exploring Projected Health Status, Medical Spending and Long-Term Care Spending for Japan's 50+ Population). We also acknowledge Professor Kenji Shibuya at the University of Tokyo for the data usage of NLSNEP and Vital Statistics (supported by Ministry of Health Labour and Welfare 2016 research grant for global health problem and research).
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Appendix

Data sources

National Longitudinal Survey of Middle-aged and Elderly People (NLSMEP)

National Longitudinal Survey of Middle-aged and Elderly People (NLSMEP) follows a national representative sample of 23 thousand Japanese in age of 50-59 as of 2005 annually. It is still going on and currently 11th wave of NLSMEP was done as of the year 2015. We used 1st through 8th waves for estimation in this study. NLSMEP consists of demographics, 6 comorbid conditions (heart disease, hypertension, hyperlipidemia, stroke, diabetes, and cancer of any kind), functional limitation in activities of daily life, depression (K6 questionnaire), self-reported health, earnings, work status, work classification, retirement age, education, smoking status, marital status, and expenditure (household, medical).

Japanese Study of Ageing and Retirement (JSTAR)

Japanese Study of Ageing and Retirement (JSTAR) covers 3.7 thousand Japanese in age of 50-75 as of 2007 in 5 municipal cities for 3 waves. We extended the range of age cohorts up to 75 years old using JSTAR. As another role, JSTAR reinforces information for ADL, IADL and cognitive function, which are limited in NLSMEP. JSTAR has 19 comorbid conditions and ADL and IADL variables. ADL and mobility questions are verbatim translation from SHARE. IADL measurement in JSTAR is Tokyo Metropolitan Institute of Gerontology Index of IADL, which is most widely used, validated scale of IADL in Japan, overlapping items with IADL measurement in HRS, SHARE, and ELSA (Fujiwara, et al. 2010).

Vital Statistics

Vital Statistics provides individual mortality records with gender, age, and the leading cause of death in ICD-10 code. It is a complete survey for Japanese living in Japan, collected by Ministry of Health, Labour and Welfare. Years 2005 through 2012 are available in the data format. Occupational and industrial information are additionally available in 2005 and 2010, which are the years of Population Census. NLSMEP does not contain mortality exit information, and JSTAR does so only partially. We relied government's vital statistics records to obtain the age-sex specific proportion by leading cause of death between the period of 2005-2012 to reflect trend change of death causes and mortality. We currently consider the probabilities of death from heart disease, cancer, and stroke since they are the three main causes of death in Japan.

Appendix Table1. Definition of variables in NLSMEP and JSTAR

Data source		NLSMEP (aged 50-67)	JSTAR (aged 50-79)
Demographic	Age	Birth year (1945-1955)	Birth year (1930-1957)
	Gender	1: male / 2: female	1: male / 2: female
	Education	1: Middle school 2: High school 3: Vocational school 4: Com colledge 5: University 6: Graduate school 7: Other	1: Elementary/middle school 2: High school 3: Junior college 4: Vocational school 5: University 6: Graduate school (Master's) 7: Graduate school (Ph.D) 8: Other
	marital status	(1st wave) 1: living with his/her spouse 2: separated 3: divorced or widowed 4: never married	(1st wave) marital or common-law partnaer 1: yes (exist) 2: no marital history of the solitary 1: never married 2: widowed 3: divorced 4: don't know 5: refused to answer
	Smoke	(1st wave) 1: currently smoke 2: smoked in the past, but I have quit 3: never smoked regularly	(1st wave) 1: currently smoke 2: smoked in the past, but I have quit 3: never smoked regularly
Health status	heart disease hypertension hyperlipidemia stroke diabetes cancer	1: diagnosed 2: not diagnosed V: unknown or refused to answer	(1st wave) 0: not diagnosed 1: diagnosed (2nd and 3rd waves) 1: newly diagnosed 2: fully recovered once but recurred in the past 2 years 3: still be treated 4: fully recovered / never diagnosed
ADL limitation	walk get up	0: no problem 1: having difficulty but no help 2: needing someone's help	1: yes (has difficulty) 2: no

	dress feed toilet bath		

Appendix Table2. Variable creation for paneled logit models

Panel estimator	Transition matrix A	Transition matrix B
Data source	NLSMEP (aged 50-67)	JSTAR (aged 50-79)
Sample size	n=30,837	n= 10,071
Gender	1: male 0: female (mean: 0.48)	1: male 0: female (mean: 0.50)
Education	1: college education or higher 0: otherwise (mean: 0.16)	1: college education or higher 0: otherwise (mean: 0.12)
Marital status	1: married as of the 1st wave 0: otherwise (mean: 0.87)	1: married as of the 1st wave 0: otherwise (mean: 0.82)
Smoke	1: ever smoke as of 1st wave 0: otherwise (mean: 0.51)	1: ever smoke as of 1st wave 0: otherwise (mean: 0.46)
Health status (Note)	1: newly diagnosed or diagnosed at least once in the past 0: otherwise	1: newly diagnosed or diagnosed at least once in the past 0: otherwise
ADL limitation	1: needing at least one help 0: otherwise	1: having at least one difficulty 0: otherwise

Note: (i) For NLSMEP, we interpolated health status by the previous answer when the respondents refused to answer. For instance, if a respondent answered he/she was never diagnosed as a cancer patient ("2: not diagnosed") in the 1st wave, refused to answer ("V: unknown or refused to answer") in the 2nd and 3rd waves, and "1: diagnosed" in the 4th wave, then we indicated "0: otherwise" in the 1st, 2nd, and 3rd waves, and "1: newly diagnosed or diagnosed at least once in the past" in the 4th wave.
(ii) For JSTAR, when the respondents chose "1:Newly diagnosed with or indicated", "2:Fully recovered once but recurred in the past 2 years", or "3: Still be treated" in the 2nd and 3rd waves, we indicated "1: newly diagnosed or diagnosed at least. "

Appendix Table 3. Estimated population from NLSMEP vs simulated population (male)

Male	Group1. Heasrt Disease		Group2. Cancer		Group3. Stroke		Group4. Others	
Year	observed	simulated	observed	simulated	observed	simulated	observed	Simulated
2005(age:50-59)	328,106	331,422	129,224	122,340	126,319	122,502	8,876,960	8,884,345
2006(age:51-60)	463,782	500,505	178,856	233,992	161,184	170,813	8,605,037	8,512,158
2007(age:52-61)	561,239	566,839	235,407	251,596	200,354	187,215	8,354,178	8,353,976
2008(age:53-62)	650,474	624,062	283,104	273,923	234,149	199,284	8,124,015	8,201,809
2009(age:54-63)	721,280	693,029	351,767	304,053	265,097	214,243	7,890,073	8,023,364
2010(age:55-64)	808,803	776,422	413,949	342,952	279,494	232,366	7,658,975	7,814,639
2011(age:56-65)	883,616	876,527	485,947	392,159	301,833	253,390	7,417,325	7,570,139
2012(age:57-66)	981,198	993,832	572,821	449,614	313,260	277,396	7,141,650	7,289,449

Appendix Table 4. Estimated population from NLSMEP vs simulated population (female)

Female	Group1. Heasrt Disease		Group2. Cancer		Group3. Stroke		Group4. Others	
Year	observed	simulated	observed	simulated	observed	simulated	observed	Simulated
2005(age:50-59)	162,760	156,623	197,402	193,685	74,288	72,369	9,156,604	9,168,377
2006(age:51-60)	235,910	249,869	249,531	308,944	104,211	110,526	8,977,215	8,901,713
2007(age:52-61)	307,375	291,038	311,566	335,546	128,797	125,008	8,794,030	8,793,087
2008(age:53-62)	363,130	328,775	361,743	367,893	149,713	136,662	8,639,562	8,683,756
2009(age:54-63)	420,480	375,576	412,831	409,542	169,864	151,113	8,481,739	8,551,128
2010(age:55-64)	466,828	433,018	489,271	461,257	188,135	169,310	8,311,325	8,391,536
2011(age:56-65)	537,177	503,724	571,494	524,088	205,061	190,622	8,109,659	8,200,685
2012(age:57-66)	604,388	588,847	686,342	599,038	232,806	215,745	7,863,802	7,974,911

Appendix Table 5. Observed number of death in Vital Statistics and simulated number of death (male)

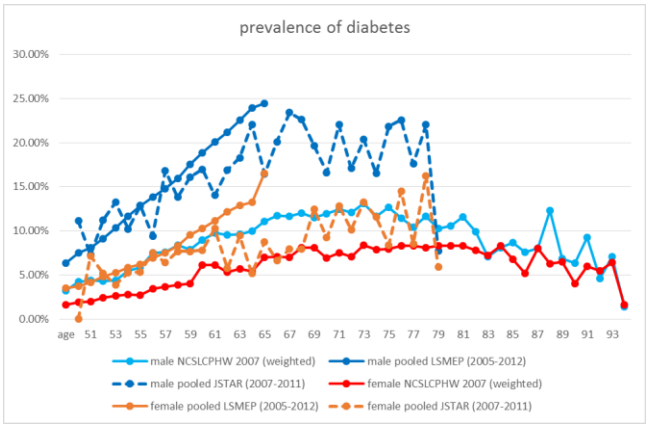
Male	Group1. Heasrt Disease		Group2. Cancer		Group3. Stroke		Group4. Others	
Year	observed	simulated	Observed	simulated	observed	Simulated	observed	Simulated
2005(age:50-59)	7,601	5,872	20,299	12,526	4,841	3,548	20,957	21,195
2006(age:51-60)	7,771	8,172	22,034	22,823	5,008	4,588	20,920	22,259
2007(age:52-61)	8,042	8,636	24,480	23,536	5,072	4,860	21,842	23,516
2008(age:53-62)	8,958	9,063	26,635	25,111	5,386	5,090	22,546	25,125
2009(age:54-63)	9,245	9,836	28,962	27,325	5,587	5,107	23,868	26,042
2010(age:55-64)	9,993	10,508	31,583	29,950	5,947	5,618	25,699	28,088
2011(age:56-65)	10,509	11,589	34,434	34,705	5,931	5,938	28,287	29,692
2012(age:57-66)	11,262	13,222	37,030	39,682	6,262	6,373	27,471	31,178

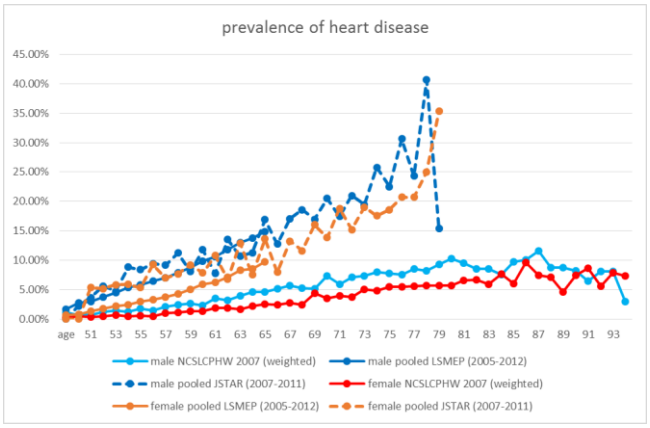
Appendix Table 6. Observed number of death in Vital Statistics and simulated number of death (female)

Female	Group1. Heasrt Disease		Group2. Cancer		Group3. Stroke		Group4. Others	
Year	observed	simulated	observed	simulated	observed	simulated	observed	Simulated
2005(age:50-59)	2,045	1,501	13,735	9,499	2,223	1,864	6,778	7,138
2006(age:51-60)	2,136	2,090	14,269	14,272	2,264	2,467	7,089	7,544
2007(age:52-61)	2,146	2,354	15,244	14,658	2,209	2,447	7,431	8,134
2008(age:53-62)	2,353	2,487	16,175	15,805	2,332	2,613	7,712	8,822
2009(age:54-63)	2,416	2,598	16,485	17,589	2,435	2,539	8,019	9,512
2010(age:55-64)	2,741	2,901	18,113	20,062	2,393	2,731	8,921	10,308
2011(age:56-65)	3,039	3,269	19,161	23,219	2,588	2,934	11,264	11,156
2012(age:57-66)	3,204	3,843	19,861	27,333	2,603	3,297	10,137	12,107

Appendix Figure1. Comparison of disease prevalence by age and gender among LSMEP, JSTAR, and NCSLCPHW

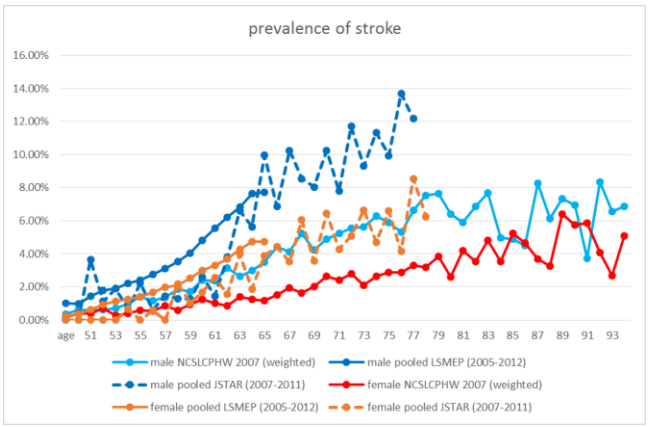
(a) diabetes (b) heart disease

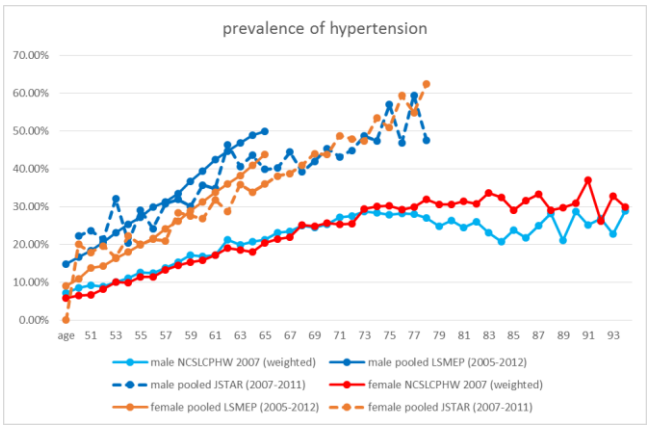




(c) stroke

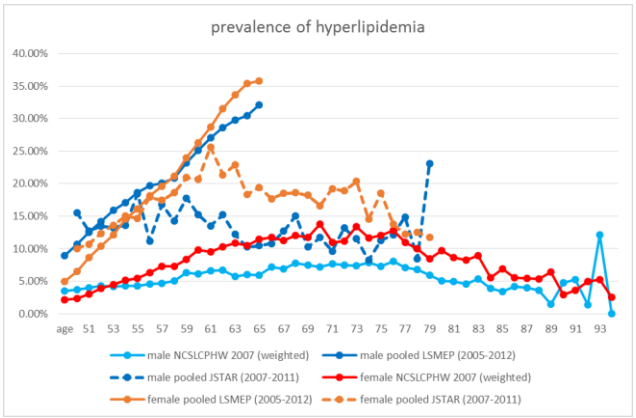
(d) hypertension

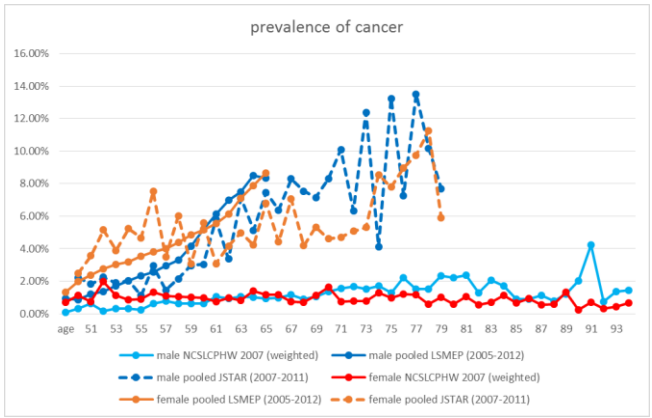




(e) hyperlipidemia

(f) cancer





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Perspective

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INTERNATIONAL HEALTH CARE SYSTEMS

The Future of Japan's Health System — Sustaining Good Health with Equity at Low Cost

Michael R. Reich, Ph.D., and Kenji Shibuya, M.D., Dr.P.H.

Four years ago, Japan celebrated 50 years of achievement of good health at low cost and increasing equity for its population.[1] In 1961, at the beginning of a period of rapid economic development, while the country was still relatively poor (with a gross domestic product [GDP] half the size of Britain's), Japan reached full health insurance coverage of its population. In the next half-century, it continued to develop its health system and improve equity, even applying this principle of universal health coverage in its global health diplomacy.[1] Now, however, Japan faces serious fiscal pressure due to a sluggish economy and the rapid aging and low birth rate of its population — but it is striving to sustain its health system in the face of these challenges.

An interactive graphic is available at NEJM.org

Japan followed a nonlinear path to universal coverage. Previous Japanese policymakers were sometimes motivated to develop the health system for reasons of political economy that were unrelated to health. For example, Japan's first national policy for health insurance was introduced in 1923, motivated in part by imperial visions and the desire for a strong and healthy workforce for war. During World War II, Japan achieved nearly 70% health insurance coverage. Then, in the postwar period, political competition among the major parties promoted government efforts to expand coverage, as the conservative Liberal Democratic Party sought to provide benefits to its rural constituents and to weaken the agendas of the Socialist and Communist parties by redistributing social resources to industrial workers. Japan was not unique in this regard: in countries such as Britain and Germany, the process of attaining universal health coverage also stretched over long periods and was advanced by various political motivations.[2] Though such mixed origins don't diminish the value of Japan's health policy accomplishments, they do highlight the importance of viewing the process from historical and political perspectives.

Japan's achievements in health status are well known (see table). Since 1986, Japan has ranked first in the world in women's life expectancy at birth, which reached 87 years in 2014. Life expectancy

Selected Characteristics of the Health Care System and Health Outcomes in Japan.*

Variable	Value
Health expenditures in 2013	
Per capita (U.S. $)	3,966
Percentage of GDP	10.3
Out-of-pocket (% of private health expenditures)	80.2
Public sources (% of total)	82.1
Health insurance	
Percent of population covered	>99.9
Funding sources	Taxes and premiums
Access	
Hospital beds per 10,000 population in 2013 (no.)	133
Physicians per 1000 population in 2012 (no.)	2.3
Percent of total government health expenditures spent on mental health care in 2011	4.9
Clinics using electronic medical records in 2011 (%)	20.9
Physicians' average monthly income in 2013 (U.S. $)	11,769
Life and death	
Life expectancy at birth in 2013 (yr)	83.5
Additional life expectancy at 60 yr in 2013 (yr)	25.9
Deaths per 1000 population in 2013 (no.)	10.1
Infant deaths per 1000 live births in 2013 (no.)	2.1
Deaths of children <5 yr of age per 1000 live births in 2013 (no.)	3.0
Maternal deaths per 100,000 live births in 2013 (no.)	3.4
Fertility and childbirth	
Average births per woman in 2014 (no.)	1.4
Births attended by skilled health staff in 2013 (%)	99.8
Preventive care	
Colorectal-cancer screening generally available at primary care level	Yes
Children 12–23 mo of age receiving measles immunization in 2013 (%)	95.5
Prevalence of chronic diseases (%)	
Diabetes in persons 20–79 yr of age in 2014	5.1
HIV infection	<0.1
Prevalence of risk factors (%)	
Obesity in adults ≥20 yr of age in 2013	3.7
Smoking in adults ≥20 yr of age in 2013	19.3

* Data are from the Organization for Economic Cooperation and Development; the World Bank, Hashimoto et al.[3]; the Japan Ministry of Health, Labor, and Welfare; the World Health Organization; and the National Institute of Population and Social Security Research. GDP denotes gross domestic product, and HIV human immunodeficiency virus.

for Japanese men surpassed 80 years in 2013. Japan's infant mortality rate, reported as 2.1 per 1000 live births in 2013, is the lowest in the world. But a continuing decline in birth rate means that the country's population is shrinking, even as it ages more rapidly than in other societies. The proportion of people older than 65 years increased from around 12% in 1990 to 25% in 2013, and the proportion of older people has exceeded the proportion of young people (0 to 14 years of age) since 1997. This demographic transition has created huge fiscal and health care challenges.

In addition to improving health outcomes, Japan's social insurance system has made incremental improvements in equity through cross-subsidies and tax transfers, which contributed to income redistribution in addition to risk pooling. As many countries have done, Japan expanded health coverage population group by population group, through policies designed for different groups with differing levels of coverage (both in terms of benefits and funding) — thereby creating disparities and problems of fairness. Government action and new social policy were required in order to reduce these inequities. Japan's single reimbursement fee schedule (for all physicians and patients) and single benefit package for all social insurance programs created a foundation for equity in access. The government then increased equity by changing the copayment policies for the various insurance programs, reducing benefits for employees of private companies (by increasing their copayment rates), and increasing benefits for the elderly and non–employment-based insurance plans (by reducing their copayment rates). Policymakers thus made the overall health system more equitable over time, reflecting the value that Japanese society places on egalitarianism.

Those achievements in equity are now at risk. Japan still has about 3500 insurance plans, with

MYOCARDIAL INFARCTION

A 55-year-old man with no serious health conditions has a moderately severe myocardial infarction.

In his suburban Tokyo home, Tanaka-san wakes up one day with chest pain. When the pain continues for 30 minutes, his family becomes worried and calls an ambulance, which arrives in 5 minutes. The emergency medicine team contacts the dispatcher, who asks a neighborhood general hospital whether there is room for an admission but is told that the coronary care unit is full. After 30 minutes of calls, the dispatcher finally finds a private hospital (with 150 beds) 20 minutes away that is willing to accept the patient.

This hospital has heart catheterization, MRI, and other equipment, and the emergency doctor in charge obtains an electrocardiogram and serum enzyme test to diagnose a myocardial infarction. A cardiologist is called to perform a cardiac catheterization, which reveals an infarction of a high lateral branch of the left anterior descending artery. A stent is immediately inserted, and reperfusion is established. The patient then stays in the hospital for 2 weeks.

The total hospitalization fee reaches ¥1.5 million (U.S. $12,000, including two heart stents for $6,700 and facility fees of $2,500). Coverage from Japan's High-Cost Medical Care Benefit System allows Tanaka-san to pay only $1,300, to cover the fee for a single-bed room for a few nights, insurance copayments, and some extra meal fees.

The day before discharge, Tanaka-san receives instructions on medication and lifestyle counseling. He is instructed to visit the outpatient clinic 2 weeks later. Because the hospital is far from his home, the patient asks for an introduction to a nearby general practitioner. Eight months later, however, follow-up angiography to see whether any restenosis has occurred has still not been done.

Hideki Hashimoto, Masayo Matsuzaki, and Mikko Kanda contributed to this case study.

varying premium levels, so some private companies or municipalities provide better financial benefits than others. The fragmented insurance plans are differentially affected by the increasing number of elderly people in Japan. As people age and retire, they move from employment-based plans to non–employment-based plans, whose costs per person increase as older enrollees are added. As a result, non–employment-based plans increasingly have financial problems, especially as compared with Japan's employment-based plans. In an effort to reduce the financial problems for these plans and address the needs of the aging population, Japan introduced a national policy for long-term care insurance in 2000, and in 2008, it created a new health insurance program for people over 75 years of age.

Rising health care costs are a serious concern in Japan today: if the country takes no action, health expenditures could increase from the current 8% of GDP to around 11% by 2025.[4] Rising costs are a result of structural problems in the health system, especially the rapidly aging population and the frequent use of high-cost technologies such as magnetic resonance imaging and relatively high-priced generic medicines (which cost 60% of brand-name prices in Japan). Two decades of economic stagnation during the 1990s and 2000s (the "lost decades") also mean that health care costs have been taking a proportionately greater bite out of the GDP.

A final major challenge involves improving the quality of care in the Japanese system. Quality and efficiency have often been ignored by Japan's health policies. Existing government programs tend to focus on quantifying inputs and structures rather than on creating incentives to improve quality or addressing problems in outcomes. Some studies have suggested that postsurgical mortality rates in large hospitals in Japan are as low as those reported in other countries but that the quality of primary care and inpatient chronic care services may be problematic.[3] Japanese hospitals and clinics are poorly differentiated by level of services, and there is no standardized benchmarking to assess hospital performance.

The Japanese government is acutely aware of these challenges and the intersecting crises of rapid aging and fiscal sustainability, which are further confounded by the health system's complex governance, including the mechanism for defining the fee schedule, as well as people's changing expectations about both medical and nonmedical aspects of health care.[1] The government is trying

PREGNANCY AND CHILDBIRTH

A healthy 23-year-old woman is pregnant for the first time.

Suzuki-san is married and lives in a Tokyo suburb. Realizing that she is pregnant, she goes to a neighborhood hospital to consult an obstetrician, who confirms the pregnancy, and she pays him ¥8,000 (U.S. $64), since pregnancy is not covered by Japan's national health insurance.

Suzuki-san next visits the nearby municipal health center. She notifies the authorities about her pregnancy and receives the Mother and Child Health Handbook, to record information from the physician's medical examination, any concerns about the pregnancy, observations about the newborn baby, and ongoing observations about the infant. She also receives a pregnancy health checkup consultation ticket and an ultrasound inspection visit ticket, which provide her with partial financial support for these antenatal services.

During her pregnancy, Suzuki-san follows the typical schedule of 14 visits for health checkups at her hospital. At each visit, she is examined by the obstetrician for risks and symptoms of pregnancy complications and meets with the midwife for nutritional and mental health care and support.

At 20 weeks, she decides on a hospital and on a vaginal delivery. After the birth, Suzuki-san stays as an inpatient for 5 days. She pays a total of ¥620,000 ($5,000) for all hospital services and is reimbursed by health insurance for ¥420,000 ($3,400).

Two weeks after the birth, a midwife will visit Suzuki-san at home at no charge. Two weeks later, Suzuki-san will bring her infant to the hospital where she gave birth, where she will see an obstetrician-gynecologist and her child will see a pediatrician.

Hideki Hashimoto, Masayo Matsuzaki, and Mikko Kanda contributed to this case study.

to find ways to ensure fiscal sustainability, in response to the commitment made by Prime Minister Shinzō Abe to eliminate deficits by 2020. Recent laws seek to promote both the differentiation of hospitals by function and the community-level integration of medical treatment, long-term care, and preventive care by 2025. Japan is also considering a proposal to consolidate insurance plans at the prefectural level. In 2014, the Abe cabinet endorsed a government health care strategy that aims to facilitate the development of innovative technologies through a new Agency for Medical Research and Development. But these changes are not likely to be sufficient to address the profound fiscal and demographic problems facing the country. Maintaining Japan's current system by increasing premiums or taxes while cutting benefits, as was done in the past, might buy some time — but it would be very costly politically and would not resolve fundamental structural problems. Incremental changes at the margins will no longer suffice.

Instead, we believe that Japan needs a new vision of health care and health systems for the future. In June 2015, an advisory panel of young experts, appointed by Health Minister Yasuhisa Shiozaki, presented its vision of health care for Japan in 2035.[5] The panel's report proposes a paradigm shift for Japan's health system, to redirect its focus from inputs to outcomes, from the quantity of services provided to patients' concerns about quality, from governmental regulation to professional self-regulation, from cure to care and well-being, and from specialization of services to integrated approaches across medical and social service sectors. The new health system would continue to emphasize fairness and solidarity, while building on individual patient values and desires and emphasizing global health perspectives.[5] The government, recognizing that Japan needs new solutions for its profound problems, has explicitly called on the younger generation to produce innovative ideas for improving the health system.

The hope is that Japan will be able to mobilize new ideas, systems, and technologies to assist its growing elderly population and conform to changing social values and growing structural constraints and that the Japanese government will be able to jumpstart the economy and get it growing again (using Prime Minister Shinzō Abe's strategies of government spending, monetary easing, and structural reforms, known as "Abenomics"), even as the population continues to age and shrink. More and more countries are confronting similar challenges, but Japan is first in line. Accomplishing these multiple and sometimes conflicting goals will not be easy, but that's the challenge that Japan's health system and society must tackle.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

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New Math on Drug Cost-Effectiveness

Peter B. Bach, M.D., M.A.P.P.

Related article, p. 1803

Nowadays, the reality of exorbitant drug pricing overshadows even the most exceptional stories of drug efficacy. It's true that we're making huge biomedical strides, yet it's also true that prices for new drugs are rising, as are prices of existing treatments.

A case in point is nivolumab, which, as Motzer et al. report in this issue of the *Journal* (pages 1803–1813), appears to extend median survival in patients with metastatic renal-cell cancer by nearly half a year. But the cost to insurers and patients of using the drug for this condition — by my estimate, around $65,000 for Medicare beneficiaries and up to twice that for commercially insured patients — can't be ignored.

The price hurts patients, limiting their access and depleting their savings. Under the current system of insurance, many patients have to pay large sums out of pocket, and research shows that when that happens, some patients will stop taking medications even if they are very effective.[1] The high costs of cancer care also drive patients into bankruptcy.

The problem is particularly acute for Medicare beneficiaries, who account for the majority of patients with cancer in the United States. For nivolumab, a drug categorized as physician-administered and thus insured under Medicare's Part B benefit, Medicare assigns 20% of the cost to the patient. Although most Medicare beneficiaries have extra insurance to cover this expense — through Medicaid, an employer-based plan, or a private-market product such as Medigap — approximately 15% do not, according to the 2011 Medicare Current Beneficiary Survey. In other words, a sizable number of Medicare patients receiving this treatment could owe about $13,000 — more than half the typical annual median income among Medicare beneficiaries, which is $24,150 (Medicare beneficiaries who lack additional coverage actually tend to have incomes below this level).

Exacerbating this problem, Medicare sets no upper limit on coinsurance under Part B (or under Part D) even though commercial plans regulated under the Affordable Care Act do have out-of-pocket maximums. Federal law prevents the maker of nivolumab (Bristol-Myers Squibb) from providing assistance to patients who cannot afford the treatment. Programs such as Genentech's for Avastin, in which beneficiaries receive the drug free once they have spent a certain amount in a calendar year, are rare.[2]

Policymakers, stymied by the rising cost of drugs, might think that an approach that relies on cost-effectiveness analyses would help the health care system deal with the high price of new treatments. After all, the United Kingdom sets standards for cost-effectiveness at about $40,000 per quality-adjusted life-year for new drugs, and overall health care spending there is a fraction of what it is in the United States.

Of course, this potential solution remains theoretical today, since Medicare cannot limit drug access on the basis of cost-effectiveness; rather, laws require Medicare to cover all cancer drugs for all uses approved by the Food and Drug Administration (FDA) or listed in recognized compendia and to pay the price the manufacturer chooses to charge. But even if Medicare could set such limits, I believe that policymakers would find limited relief from the approach.

Expensive drugs can still seem deceptively cost-effective, because of the long upward spiral we have seen in the prices of cancer treat-

PLOS ONE

RESEARCH ARTICLE

Health Insurance Coverage and Hypertension Control in China: Results from the China Health and Nutrition Survey

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Abstract

Background

China has rapidly expanded health insurance coverage over the past decade but its impact on hypertension control is not well known. We analyzed factors associated with hypertension and the impact of health insurance on the management of hypertension in China from 1991 to 2009.

Methods and Findings

We used individual-level data from the China Health and Nutrition Survey (CHNS) for blood pressure, BMI, and other socio-economic variables. We employed multi-level logistic regression models to estimate the factors associated with prevalence and management of hypertension. We also estimated the effects of health insurance on management of hypertension using propensity score matching. We found that prevalence of hypertension increased from 23.8% (95% CI: 22.5–25.1%) in 1991 to 31.5% (28.5–34.7%) in 2009. The proportion of hypertensive patients aware of their condition increased from 31.7% (28.7–34.9%) to 51.1% (45.1–57.0%). The proportion of diagnosed hypertensive patients in treatment increased by 35.5% in the 19 years, while the proportion of those in treatment with controlled blood pressure remained low. Among diagnosed hypertensives, health insurance increased the probability of receiving treatment by 28.7% (95% CI: 10.6–46.7%) compared to propensity-matched individuals not covered by health insurance.

Conclusions

Hypertension continues to be a major health threat in China and effective control has not improved over time despite large improvements in awareness and treatment access. This suggests problems in treatment quality, medication adherence and patient understanding of the condition. Improvements in hypertension management, quality of medical care for those at high risk, and better health insurance packages are needed.

Competing Interests: The authors have declared that no competing interests exist.

Introduction

In China, hypertension is the second most common disease risk factor [1]. Approximately 177 million people are estimated to be living with hypertension, with relatively low rates of awareness and control of this condition. [2,3] Previous studies have shown that public health services may be making little contribution in informing patients of their hypertensive status, [4] and more research is needed to understand how the response to this disease can be improved in the context of a rapidly changing health system and an aging population. Also, although some research on hypertension management in China has been conducted, the direct associations of health insurance on hypertension management still remain unknown.

China's health insurance coverage has increased rapidly from 45% in 2006 to around 90% in 2009, [5] but the effectiveness of health insurance packages for hypertensive patients is not yet well understood at the population level, even though some contain special measures for severely hypertensive patients. [6] Given China's rapid development over the past decade and the changes in health insurance coverage over the last five years, it is essential to evaluate the impact of health insurance on hypertension management and control.

In this article we had three main objectives:

- Estimating the prevalence of hypertension in China during the period of the CHNS;
- Estimating the proportion of those with prevalent hypertension who were aware of their disease, receiving treatment for it, or had controlled blood pressure;
- Estimating the effect of increased health insurance coverage on the management of hypertension.

Method

Data sources

We used datasets from the China Health and Nutrition Survey (CHNS), a cohort study established in 1989 with a total of eight survey waves in nine provinces until 2009. From 1989 to 2009, the CHNS collected data over a total of eight waves in nine provinces: Guangxi, Guizhou, Heilongjiang, Henan, Hubei, Hunan, Jiangsu, Liaoning, and Shandong. A stratified, multistage cluster sampling process was used to select samples in each of the provinces. Counties in each province were stratified according to income (low, middle, and high), and four counties in each province were selected using probability sampling. In each province, the capital city and a low-income city were selected if possible, although in two provinces large cities other than capitals had to be selected. Within these primary sampling units, villages, townships and urban/suburban neighborhoods were selected randomly. From 1989 to 1993 there were 190 primary sampling units: 32 urban neighborhoods, 30 suburban neighborhoods, 32 towns (county capital city), and 96 rural villages. After 2000, this increased to 216 units comprised of 36 urban neighborhoods, 36 suburban neighborhoods, 36 towns, and 108 villages. [7]

In this study, we used a repeated cross-sectional design, focusing on only new subjects above 35 years old in each wave for two reasons: First, physical exams in previous waves may have some effect on the awareness of high blood pressure in study subjects; secondly, the population under 35 has low prevalence of hypertension and hypertension in this age group may reflect very different risk factors. We excluded the first (1989) wave because the blood pressure testing method was different in this wave and information on some other socioeconomic variables was missing. Participants without fully recorded blood pressure testing results in other waves were also excluded in this study. For propensity score matching, we also took out participants who did not have socioeconomic variables that we used for matching.

Statistical analysis

Multi-level logistic regression models were used in this analysis. We modeled a household-level random intercept to adjust for the genetic and socio-economic similarities within one family. The four outcomes in these models were:

1. *Prevalence*, defined as hypertension diagnosed at the time of entry into the study cohort or normal blood pressure readings in a subject currently taking anti-hypertensive medication. Hypertension was defined as average systolic blood pressure of the second and third of three tests≥140 mm Hg, or average diastolic blood pressure of the second and third test≥90 mm Hg;
2. *Awareness*, defined as a self-report of medically-diagnosed hypertension among subjects with hypertension;
3. *Treatment*, defined as people aware of their hypertension who were receiving anti-hypertensive medication treatment; and
4. *Control*, defined as normal blood pressure among people who were receiving treatment

Predictors tested in this model were sex, obesity, age and region of residence; study wave; education; income; presence of health insurance; smoking and alcohol use. Household per capita income in Yuan, inflated to 2009 values (1 US dollar = 6.83 Yuan), [8] was used as the income predictor in the model, divided into quintiles. Standardized prevalence of hypertension was also calculated to adjust for changes in the age distribution of new entrants over time. Since no information on probability weights is provided in the CHNS, no probability weights were used in this model. [7] We retained all possible predictors in our final regression model including those that were not statistically significant.

Propensity score matching

We employed propensity score matching to estimate the average effects of health insurance on the management and control of hypertension. Propensity score matching is a process to adjust the data by matching the treated group to a control group that is defined as similar according to a propensity score developed based on background characteristics. [9] After propensity score matching, the comparability between the treatment variable (in this study, health insurance) and confounder variables is enhanced. By reducing the link between treatment variable and background variables through propensity score matching, regression results are less model-dependent and have reduced potential for bias. [9]

For the propensity score matching analysis, we used the k-Nearest neighbors matching method with five neighbors and matched individuals having health insurance with individuals who did not have health insurance using a propensity-score calculated based on study wave, age, sex, province, residency, income, and education level. One-to-one matching was used for sensitivity analysis, and found the similar results.

Results

Demographic characteristics of the sample

A total of 25,936 new subjects were involved in the CHNS until 2009. From these 1609 (6.2%) new participants in wave 1989 and 14,356 (55.4%) subjects aged under 35 or with no age information were removed. Finally, a total of 9971 (38.4%) subjects were used in our study with a mean age of 52.5 (range 35.0 to 96.5 years old). Table 1 shows the descriptive statistics of the

Table 1. Demographic and socio-economic properties of the sample.

	Frequency	Proportion (%)
Wave		
1991	4532	45.5
1993	414	4.2
1997	1705	17.1
2000	738	7.4
2004	1029	10.3
2006	475	4.8
2009	1078	10.8
Gender		
Male	4826	48.4
Female	5145	51.6
Province		
Liaoning	1113	11.2
Heilongjiang	914	9.2
Jiangsu	1160	11.6
Shandong	1293	13.0
Henan	1202	12.1
Hubei	874	8.8
Hunan	968	9.7
Guangxi	1297	13.0
Guizhou	1150	11.5
Residency		
Urban	3931	39.4
Rural	6040	60.6
Age		
35–44	3465	34.8
45–54	2572	25.8
55–64	2164	21.7
65–74	1221	12.3
$\geq$75	549	5.5
BMI		
Normal	6488	65.1
Underweight	774	7.8
Overweight	1948	19.5
Obese	761	7.6
Smoking history		
None or past smoker	6470	66.1
Current smoker	3313	33.9
Alcohol use frequency		
None	6095	62.3
No more than 2 times a week	1948	19.9
More than 2 times a week	1738	17.8
Health insurance		
No	6221	62.6
Yes	3714	37.4
Education		
Not graduated from primary school	3729	38.6

(*Continued*)

Table 1. (*Continued*)

	Frequency	Proportion (%)
Graduated from primary school	2138	22.1
Graduated from middle or high school	3042	31.5
Tertiary education	765	7.9

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study sample. The health insurance coverage rate in this sample was 37.4%, and 45.5% of the total sample came from the 1991 wave.

Prevalence of hypertension

Table 2 shows prevalence of hypertension along with multi-level logistic regression analysis results. Prevalence of hypertension among the whole sample was 28.3% (95% CI 27.3–29.2%) and increased to 31.5% (28.5–34.7%) in 2009. Trends in prevalence of hypertension were unchanged after standardization using the WHO Standard Population as a reference distribution. Age was significantly positively associated with prevalence of hypertension, and more than half of elderly individuals (over 65 years old) had hypertension. Consistent with previous studies, women had lower prevalence of hypertension than men with odds ratio 0.67 (95% CI 0.57–0.79). Obesity increased the odds ratio of being hypertensive by a factor of 4.48 (3.41–5.89). Heavy drinking was also positively associated with prevalence of hypertension with an odds ratio of 1.34 (1.11–1.61). However, smoking and income had little effect. Compared to Liaoning province, Jiangsu, Hubei, and Guangxi provinces had lower prevalence of hypertension.

Trends in factors associated with hypertension

Fig 1 shows how trends in tobacco and alcohol use, BMI and health insurance coverage have changed over time in this survey. The smoking rate increased from 1991 to 1993, and gradually decreased after that. The obesity rate (including obesity and overweight) increased slightly from 1991 to 2009. Health insurance coverage increased over time and grew rapidly after 2006. In 2009, health insurance coverage reached around 90% in this sample.

Management and control of hypertension

Table 3 shows hypertension prevalence, awareness rates amongst hypertensives, treatment rates amongst diagnosed hypertensives, and control rates amongst medically-treated hypertensives in each wave. Fig 2 shows the trends in prevalence and outcomes of hypertension management over time. The proportion of people with hypertension who were aware of their condition gradually increased over time and reached 51.1% (95% CI 45.1–57.0%) in 2009 (Table 3). Table 4 shows the logistic regression results of management outcomes. Elderly, obese and well-educated subjects were more likely to be aware of their hypertension. Current smokers or people living in rural areas were less likely to know about their hypertension. Inequality in hypertension awareness rates was found among different provinces, with people from Jiangsu, Hubei, and Guangxi provinces more likely to be diagnosed (Table 4).

Among individuals who were diagnosed as hypertensive, treatment rates have increased rapidly from 66.2% (60.3–71.7%) to 89.7% (83.6–94.1%) over the 19 years (Table 3). Although treatment rates increased rapidly over time, only 32.1% (95% CI 24.2–40.8%) of treated people had their hypertension under control in the latest survey in 2009 (Table 3). Table 4 shows that only age and district were significantly associated with control, with older people or residents

Table 2. Prevalence of hypertension by key risk factors.

	Frequency	Proportion (%)	Odds ratio (95% CI)	P-value
Age				
35–44	385	12.1	1	NA
45–54	566	23.7	2.41 (2.02–2.88)	<0.001
55–64	790	38.6	5.67 (4.67–6.88)	<0.001
65–74	605	52.4	12.10 (9.56–15.30)	<0.001
≥75	273	55.0	16.62 (12.23–22.58)	<0.001
Wave				
1991	1040	23.8	1	NA
1993	117	29.9	1.25 (0.92–1.71)	0.2
1997	501	33.5	1.38 (1.12–1.71)	0.003
2000	229	31.5	1.14 (0.87–1.50)	0.3
2004	311	32.5	1.20 (0.95–1.52)	0.1
2006	133	31.7	1.23 (0.90–1.66)	0.2
2009	288	31.5	1.36 (1.06–1.74)	0.02
Gender				
Male	1342	30.2	1	NA
Female	1277	26.5	0.66 (0.57–0.77)	<0.001
Province				
Liaoning	420	38.1	1	NA
Heilongjiang	284	36.9	0.99 (0.73–1.33)	0.9
Jiangsu	331	30.1	0.46 (0.36–0.60)	<0.001
Shandong	410	32.4	0.63 (0.50–0.81)	<0.001
Henan	286	28.5	0.58 (0.45–0.75)	<0.001
Hubei	234	28.1	0.65 (0.50–0.86)	0.002
Hunan	207	23.6	0.56 (0.43–0.74)	<0.001
Guangxi	230	19.3	0.35 (0.26–0.45)	<0.001
Guizhou	217	19.4	0.36 (0.27–0.47)	<0.001
Residency				
Urban	1225	33.3	1	NA
Rural	1394	24.9	0.90 (0.78–1.03)	0.1
BMI				
Normal	1456	23.3	1	NA
Underweight	160	21.3	0.58 (0.46–0.75)	<0.001
Overweight	788	41.6	2.39 (2.06–2.77)	<0.001
Obesity	225	56.1	4.25 (3.24–5.58)	<0.001
Smoke				
No or used	1754	29.0	1	NA
Current smoker	810	26.5	0.83 (0.72–0.97)	0.02
Alcohol use frequency				
No	1607	28.2	1	NA
No more than 2 times a week	428	24.1	0.93 (0.79–1.11)	0.4
More than 2 times a week	530	32.4	1.29 (1.07–1.54)	0.007
Have health insurance				
No	1431	24.6	1	NA
Yes	1181	34.5	1.15 (0.99–1.32)	0.06
Education				
No graduated from primary school	1070	30.5	1	NA

(*Continued*)

Table 2. (*Continued*)

	Frequency	Proportion (%)	Odds ratio (95% CI)	P-value
Graduated from primary school	517	25.9	0.90 (0.75–1.07)	0.2
Graduated from middle or school	700	25.2	1.04 (0.87–1.24)	0.7
Tertiary education	207	29.3	0.72 (0.55–0.94)	0.02
Quintiles of income				
1	486	22.5	1	NA
2	383	24.6	1.10 (0.90–1.36)	0.4
3	597	32.0	1.25 (1.03–1.52)	0.03
4	550	30.0	1.04 (0.85–1.28)	0.7
5	590	33.0	0.98 (0.78–1.25)	0.9

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of Liaoning and Shandong provinces less likely to have their hypertension under control. There was no significant time trend in control rates amongst treated patients, and increased health insurance coverage also had little association with control.

Propensity score matching

The average treatment effects of health insurance on awareness in total were 0.05 (95% CI -0.08 to 0.19, p-value 0.2), 0.06 (-0.08 to 0.20, p-value 0.2) in urban areas and 0.01 (-0.21 to 0.23, p-value 0.5) in rural areas after propensity score matching. The average treatment effect of health insurance on treatment was 0.29 (0.11 to 0.47, p-value 0.001) in total, 0.27 (0.05 to 0.48, p-value 0.008) in urban areas and 0.27 (-0.11 to 0.65, p-value 0.08) in rural areas. The

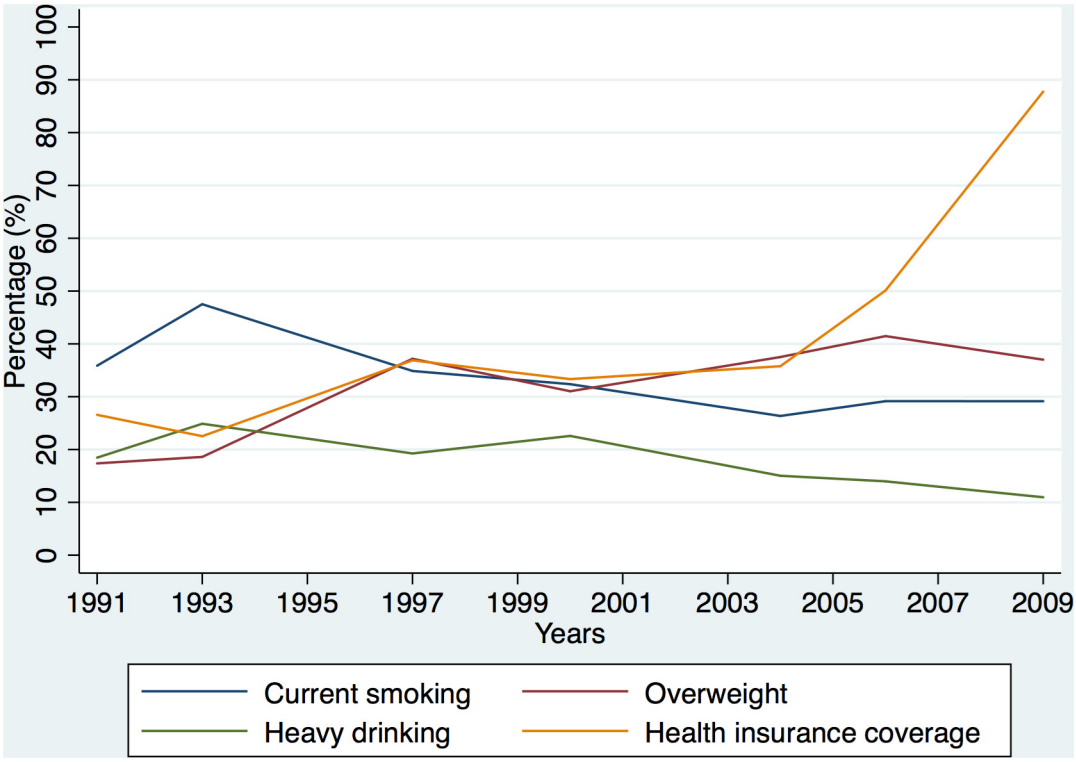

Fig 1. Trends in smoking, heavy drinking, obesity (including overweight and obesity) and health insurance coverage.

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Table 3. Prevalence, awareness, treatment and control of hypertension.

Wave	Prevalence		Awareness		Treatment		Control	
	Frequency	Proportion (95% CI) (%)	Frequency	Proportion (95% CI) (%)	Frequency	Proportion (95% CI) (%)	Frequency	Proportion (95% CI) (%)
1991	1040	23.8 (22.5–25.1)	283	31.7 (28.7–34.9)	186	66.2 (60.3–71.7)	37	19.9 (14.4–26.4)
1993	117	29.9 (25.4–34.7)	25	24.5 (16.5–34.0)	18	72.0 (50.6–87.9)	4	22.2 (6.4–47.6)
1997	501	33.5 (31.1–36.0)	124	25.1 (21.3–29.1)	101	81.5 (73.5–87.9)	33	32.7 (23.7–42.7)
2000	229	31.5 (28.1–35.0)	89	39.4 (33.0–46.1)	71	79.8 (70.0–87.6)	18	25.4 (15.8–37.1)
2004	311	32.5 (29.6–35.6)	122	39.7 (34.2–45.5)	106	86.9 (79.6–92.3)	37	34.9 (25.9–44.8)
2006	133	31.7 (27.3–36.4)	55	41.4 (32.9–50.2)	46	83.6 (71.2–92.2)	13	28.3 (16.0–43.5)
2009	288	31.5 (28.5–34.7)	146	51.1 (45.1–57.0)	131	89.7 (83.6–94.1)	42	32.1 (24.2–40.8)
Total	2619	28.3 (27.3–29.2)	844	34.6(32.7–36.5)	659	78.3(75.3–81.0)	184	27.9 (24.5–31.5)

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average treatment effect of health insurance on control was -0.12 (-0.32 to 0.09, p-value 0.9) in total, -0.07 (-0.30 to 0.16, p-value 0.7) in urban areas and -0.05 (-0.41 to 0.30, p-value 0.6) in rural areas. Health insurance showed a positive effect only on treatment, people with health insurance had a 29% higher chance to receive hypertension treatment compared to those who do not have health insurance. The effect on awareness and control was not significant, which was consistent with the logistic regression results.

Among diagnosed hypertensives, health insurance increased the probability that they would receive treatment by 28.7% (95% CI: 10.6–46.7%, p-value 0.001) compared to propensity-matched individuals who were not covered by health insurance.

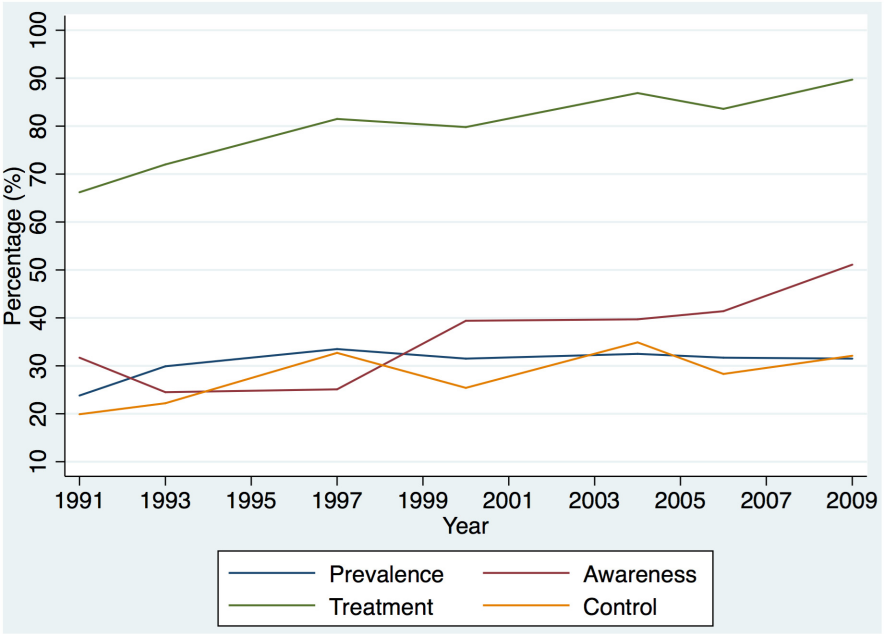

Fig 2. Trends in prevalence, awareness, treatment and control of hypertension.

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Table 4. Characteristics of management outcomes.

	Awareness		Treatment		Control	
	Odds ratio (95% CI)	P-value	Odds ratio (95% CI)	P-value	Odds ratio (95% CI)	P-value
Age						
35–44	1	NA	1	NA	1	NA
45–54	2.01 (1.37–2.95)	<0.001	1.85 (0.61–5.62)	0.3	0.44 (0.20–0.96)	0.04
55–64	3.53 (2.39–5.22)	<0.001	2.19 (0.77–6.26)	0.1	0.45 (0.22–0.95)	0.04
65–74	3.82 (2.51–5.80)	<0.001	1.31 (0.46–3.70)	0.6	0.49 (0.22–1.07)	0.07
≥75	2.95 (1.82–4.79)	<0.001	5.73 (1.05–31.30)	0.04	0.45 (0.18–1.13)	0.09
Wave						
1991	1	NA	1	NA	1	NA
1993	0.80 (0.45–1.46)	0.5	2.12 (0.45–9.99)	0.3	0.73 (0.18–3.00)	0.6
1997	0.57 (0.40–0.81)	0.002	2.88 (0.92–9.00)	0.07	1.43 (0.74–2.80)	0.3
2000	1.18 (0.76–1.84)	0.5	4.47 (1.22–16.32)	0.02	1.82 (0.78–4.25)	0.2
2004	1.11 (0.77–1.62)	0.6	4.75 (1.36–16.58)	0.02	2.03 (1.04–4.00)	0.04
2006	1.23 (0.77–1.98)	0.4	3.85 (0.91–16.23)	0.07	1.21 (0.52–2.84)	0.7
2009	1.90 (1.28–2.82)	0.001	3.78 (1.14–12.59)	0.03	1.71 (0.88–3.34)	0.1
Gender						
Male	1	NA	1	NA	1	NA
Female	1.35 (1.04–1.74)	0.02	1.18 (0.61–2.27)	0.6	0.79 (0.49–1.26)	0.3
Province						
Liaoning	1	NA	1	NA	1	NA
Heilongjiang	1.27 (0.80–2.03)	0.3	0.87 (0.26–2.77)	0.8	3.19 (1.30–7.82)	0.01
Jiangsu	1.87 (1.26–2.78)	0.002	4.99 (1.28–19.54)	0.02	2.65 (1.22–5.79)	0.01
Shandong	1.08 (0.74–1.58)	0.7	1.82 (0.66–5.02)	0.2	1.95 (0.84–4.56)	0.1
Henan	1.01 (0.66–1.55)	0.9	3.97 (1.01–15.55)	0.05	2.48 (1.05–5.89)	0.04
Hubei	1.89 (1.21–2.97)	0.005	2.67 (0.78–9.15)	0.1	3.49 (1.41–8.630)	0.007
Hunan	1.45 (0.91–2.32)	0.1	2.40 (0.69–8.34)	0.2	3.65 (1.41–9.44)	0.008
Guangxi	1.58 (1.01–2.46)	0.04	3.63 (0.91–14.40)	0.07	4.05 (1.69–9.72)	0.002
Guizhou	1.55 (0.96–2.51)	0.08	1.96 (0.54–7.17)	0.3	2.79 (1.09–7.13)	0.03
Residency						
Urban	1	NA	1	NA	1	NA
Rural	0.75 (0.60–0.95)	0.01	1.05 (0.58–1.91)	0.9	1.02 (0.68–1.56)	0.9
BMI						
Normal	1	NA	1	NA	1	NA
Underweight	0.50 (0.29–0.84)	0.01	4.22 (0.66–26.86)	0.1	0.83 (0.28–2.48)	0.7
Overweight	1.39 (1.10–1.76)	0.005	1.57 (0.84–2.95)	0.2	0.62 (0.40–0.96)	0.03
Obesity	3.04 (2.07–4.45)	<0.001	5.07 (1.29–19.84)	0.02	1.51 (0.89–2.58)	0.1
Smoke						
No or used	1	NA	1	NA	1	NA
Current smoker	0.71 (0.54–0.93)	0.01	1.00 (0.50–2.01)	1	0.86 (0.50–1.46)	0.6
Alcohol use frequency						
No	1	NA	1	NA	1	NA
No more than 2 times a week	0.92 (0.68–1.26)	0.6	1.19 (0.52–2.75)	0.7	0.81 (0.45–1.44)	0.5
More than 2 times a week	0.74 (0.54–1.02)	0.07	0.59 (0.24–1.44)	0.2	0.85 (0.43–1.67)	0.6
Have health insurance						
No	1	NA	1	NA	1	NA
Yes	1.02 (0.79–1.31)	0.9	2.81 (1.22–6.46)	0.02	0.65 (0.40–1.07)	0.09
Education						

(*Continued*)

Table 4. (*Continued*)

	Awareness		Treatment		Control	
	Odds ratio (95% CI)	P-value	Odds ratio (95% CI)	P-value	Odds ratio (95% CI)	P-value
No graduated from primary school	1	NA	1	NA	1	NA
Graduated from primary school	1.58 (1.16–2.15)	0.003	1.39 (0.61–3.14)	0.4	0.81 (0.45–1.45)	0.5
Graduated from middle or school	1.52 (1.11–2.09)	0.009	0.80 (0.34–1.88)	0.6	1.51 (0.85–2.69)	0.2
Tertiary education	1.85 (1.19–2.86)	0.006	2.88 (0.74–11.31)	0.1	1.59 (0.78–3.26)	0.2
Quintiles of income						
1	1	NA	1	NA	1	NA
2	0.89 (0.60–1.31)	0.6	0.88 (0.33–2.32)	0.8	1.39 (0.59–3.29)	0.5
3	0.97 (0.69–1.37)	0.9	1.32 (0.54–3.25)	0.5	1.16 (0.55–2.46)	0.7
4	1.12 (0.79–1.60)	0.5	1.09 (0.45–2.64)	0.8	1.82 (0.90–3.65)	0.1
5	0.98 (0.66–1.45)	0.9	1.52 (0.52–4.49)	0.4	1.56 (0.73–3.32)	0.3

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Discussion

This is the first population-based study to assess trends in the management and control of hypertension using a household survey covering 19 years of rapid change in China, which used a similar sampling and data collection method for seven consecutive waves. Trends in prevalence and management of hypertension were comparable in each wave, along with their risk factors, so the results are comparable over time and enable comparison of the periods before and after coverage of insurance increased. This is also the first study to estimate the treatment effects of health insurance on prevalence and management of hypertension in China using propensity score matching.

Prevalence of hypertension reached about 30% after 1997, which is slightly higher than found in a cross-sectional study by Gao and colleagues in 2013 based on data collected from the 2007–2008 China National Diabetes and Metabolic Disorders Study. [10] This may be because of different definitions of hypertension in these two studies. Our method of defining hypertension was slightly less restrictive than that of Gao and colleagues, and may give increased prevalence estimates relative to their findings.

According to the latest Chinese guidelines for the management of hypertension, the prevalence of hypertension has significantly increased over time. [3] However, in this study, the time trend remains stable, which may be explained in two ways. First, the data used in the 2010 Chinese guidelines came from four surveys, with different study populations, methods and definitions. Second, we only used new participants in the CHNS, who have a similar age structure in each wave. Since age is the most important determinant of prevalence, similar age structures may result in a non-significant time trend while in other surveys, the age structure is changing in the study sample along with the aging process nationwide.

Consistent with previous studies, elderly men were at higher risk of hypertension, and obesity and heavy drinking had a strong positive effect on prevalence of hypertension. [4] People with middle incomes were more likely to have hypertension, which may be attributed to their lifestyles. The CHNS study does not include comprehensive information on salt intake, but according to previous studies, salt is widely used in home cooking in China. [11] Daily salt intake is generally higher in northern areas, and more than 80% of residents take salt in excess of dietary recommendations. [12] Unobserved differences in salt intake may explain regional or wealth-based differences in hypertension in this study. Smoking rates slightly decreased over time in this study, consistent with previous national surveys. [13] Also, consistent with

previous studies, the prevalence of overweight and obesity in our study increased rapidly with rapid development in the economy and living standards in China. [14]

The awareness rate increased over time, and in the 2009 wave half of people who had hypertension were diagnosed. Although elderly and overweight people had greater awareness of their hypertensive status, the rate of awareness among these groups is still low given their much higher risk of hypertension. People living in rural areas and with lower education levels are less likely to be aware of their hypertension. This may be because these people lack the resources to obtain hypertension knowledge. Health education programs for elderly and rural populations may be effective ways to promote awareness of hypertension. [15] Differences in hypertension awareness between rural and urban areas may also relate to different types of health insurance targeting different populations. For instance, the New Rural Cooperative Medical Scheme (NCMS) covers people in rural areas while the Urban Resident/Employee Basic Medical Insurance covers people in urban areas. Our results indicate that there might be some inequity between urban and rural health insurance packages in early diagnoses of hypertension. Inequities in service utilization and health outcomes between urban and rural areas have been reported, especially in 1990s. [16]

Treatment rates amongst those diagnosed with hypertension increased to around 90% by 2009. However, among people receiving medication, the proportion of people who have actually achieved control of their hypertension was only 30%. This situation of low control of hypertension is consistent with previous studies both in China and other countries, which found limited hypertension-related knowledge, ignorance of non-pharmacological treatments, unsatisfactory medication adherence, and inappropriate medical treatment all limited the effectiveness of treatments. [3,17,18]

Although elderly people were at higher risk of hypertension, they were less likely to have controlled hypertension. This may be because systolic hypertension due to age-related factors such as arteriosclerosis was common among elderly people. [19] Previous studies have shown that it is more difficult to control systolic blood pressure than diastolic blood pressure, and combinations of two or more antihypertension drugs are required for effective treatment. [20] Also, inequalities in hypertension prevalence and management were found across provinces, which may be due to variation in lifestyles, dietary habits, health treatment costs, insurance reimbursement levels, and health promotion programs between different areas. However, there was not enough information about health policies and programs implemented at the sub-national levels, and more information and surveys are needed to explain this variation. Since prevention and management of hypertension are national health promotion goals, the inequalities across provinces indicate that stronger national-level monitoring and guidelines may be necessary to achieve national goals for hypertension control programs and policies.

Although increased health insurance coverage was significantly associated with increased levels of treatment, we found little effect of health insurance on control of hypertension. Some longitudinal studies in the US have shown a positive effect of health insurance on awareness and control of hypertension as well as drug adherence. [21] At the individual level, better health knowledge has been shown to be effective in promoting medication adherence and blood pressure control. [22] These findings indicate that there may be problems with the quality of treatment being received, access to drugs or adherence to management guidelines, together with personal health-seeking behavioral factors in China.

Hypertension, like other chronic diseases, needs long periods of outpatient treatment. However, some studies show that current Chinese medical benefit packages are still limited and mainly focus on inpatient costs. [23] A study in some provinces in China found that outpatient care for people with chronic diseases had very low reimbursement levels which indicates that people living with hypertension may receive inadequate financial support. [24] This could

affect medication adherence since previous studies have shown a positive association between lower cost of medication and better medication adherence. [25]

Although primary health centers have been proven effective in early diagnosis and management of hypertension, there are no systematic guidelines and rules for hypertensive case management at the community level in China, which may lead to low medication adherence among hypertensive patients. Some community-level studies conducted in China have shown that adherence with drug regimens is lower than 50%. [26] Regular health checks and blood pressure tests are not implemented or included in the health insurance package nationally, although some studies have shown their effectiveness in early diagnosis and management of hypertension. [27]

The main limitation of this study is that no probability sampling information is available in the CHNS. [7] This will affect the accuracy of trend analysis, but has little effect on logistic regression analysis since we used sub-samples instead of the whole sample, and merged samples in different waves, making it impossible to apply sampling weights even where they are available. Provinces involved in this study were mostly located in the northeast and middle part of China, so there were no samples from the richest and poorest provinces. However, the nine provinces chosen in this study range from the wealthiest to the poorest five, and may be relatively representative of the national income distribution. [28] Another limitation is lack of information about the method used to measure blood pressure, which may vary by wave and district. We did not include the types of health insurance in our models because the proportion of missing data on this information is too high. Also the variables we used in this study are not comprehensive, and other unobserved characteristics such as physical activity could also effect the management of hypertension. Last but not least, there is no detailed information on the methods used to recruit new participants in the CHNS, so the new households added in the sample units might not be randomly selected, although these new units should be randomly selected.

This study suggests that China's health insurance system has been effective in increasing hypertension treatment but that more needs to be done to improve effective coverage of hypertension control. Primary health care center involvement in health education, regular community-based screening, especially for high risk populations such as elderly men, and promotion of medication adherence should be considered where these interventions can be shown to be cost-effective. Also, lifestyle interventions such as reducing daily salt intake that have been proven effective in reducing blood pressure in Japan, [29] should also be considered in China. By improving public health and preventive measures in the current health insurance package, the Chinese government can act early and effectively to prevent the most serious consequences of this challenging and growing non-communicable disease epidemic.

Supporting Information

S1 Appendix. Detailed information and explanation on propensity score matching.
(PDF)

S1 Fig. Trends in age-standardized prevalence of hypertension.
(PDF)

S1 Tables. Age, gender and residency distribution over time.
(PDF)

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Author Contributions

Conceived and designed the experiments: SG. Performed the experiments: YL. Analyzed the data: YL SG. Wrote the paper: YL. Revised the manuscript: SG KS YL.

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Maternal Obesity/Pediatric Health

Maternal body mass index and risk of birth and maternal health outcomes in low- and middle-income countries: a systematic review and meta-analysis

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Summary

We conducted a systematic review and meta-analysis of population-based cohort studies of maternal body mass index (BMI) and risk of adverse birth and health outcomes in low- and middle-income countries. PubMed, Embase, CINAHL and the British Nursing Index were searched from inception to February 2014. Forty-two studies were included. Our study found that maternal underweight was significantly associated with higher risk of preterm birth (odds ratio [OR], 1.13; 95% confidence interval [CI], 1.01–1.27), low birthweight (OR, 1.66; 95% CI, 1.50–1.84) and small for gestational age (OR, 1.85; 95% CI, 1.69–2.02). Compared with mothers with normal BMI, overweight or obese mothers were at increased odds of gestational diabetes, pregnancy-induced hypertension, pre-eclampsia, caesarean delivery and post-partum haemorrhage. The population-attributable risk (PAR) indicated that if women were entirely unexposed to overweight or obesity during the pre-pregnancy or early pregnancy period, 14% to 35% fewer women would develop gestational diabetes, pre-eclampsia or pregnancy-induced hypertension in Brazil, China, India, Iran or Thailand. The highest PAR of low birthweight attributable to maternal underweight was found in Iran (20%), followed by India (18%), Thailand (10%) and China (8%). Treatment and prevention of maternal underweight, overweight or obesity may help reduce the burden on maternal and child health in developing countries.

Keywords: Low- and middle-income countries, maternal BMI, population-attributable risk, pregnancy and health outcomes.

Abbreviations: BMI, body mass index; PAR, population-attributable risk.

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Introduction

Obesity and overweight are recognized as a growing global health problem (1). Worldwide, prevalence of overweight or obesity, defined as an adult body mass index (BMI) of 25 kg m^{-2} or greater, increased by 27.5% between 1980 and 2013 (2). The proportion of overweight among adult women globally increased from 29.8% in 1980 to 38.0% in 2013, notably in developing countries (2). Patterns of overweight and obesity differ between countries, regions and by country income, with overweight or obesity more prevalent among men in developed countries and among women in developing countries (2). In developing countries, the number of deaths as a result of maternal overweight/obesity more than doubled from 336,967 deaths in 1990 to 840,427 deaths in 2010. In developed

countries, the numbers remained almost stable (739,527 deaths in 1990 to 898,040 deaths in 2010) (3). Therefore, developing countries face an increasing burden of overweight and obesity, while underweight also remains a significant health problem among women of childbearing age.

The growing epidemic of maternal overweight/obesity accounted for 1.1 million deaths and 2.3% of global disability-adjusted life years (DALYs) in 1990 and 1.7 million deaths and 4.1% of DALYs in 2010 (3,4). Several observational studies show that maternal underweight, overweight or obesity during pre-pregnancy or early pregnancy are a threat to maternal and infant health (5–14). For mothers, major adverse health outcomes are gestational diabetes, pregnancy-induced hypertension, pre-eclampsia, post-partum haemorrhage and caesarean delivery. Infants of overweight or obese mothers are at increased risk of low birthweight, preterm birth, small for gestational age and stillbirth. However, not all studies show a statistically significant relationship and there are no comprehensive assessments for each of these outcomes comparing underweight, overweight and obese mothers with normal-weight mothers using high quality cohort studies in developing countries. Maternal underweight in early pregnancy is the leading risk factor for adverse birth outcomes in developing countries, including low birthweight (8,15), preterm birth (15,16), small for gestational age (8,9,17) and stillbirths (15), but previous meta-analyses have compared these outcomes by overweight or obese versus normal-weight mothers in both developed and developing countries simultaneously (18–20). Most systematic reviews and meta-analyses are limited to the relationship between maternal BMI and specific birth and maternal health outcomes, especially gestational diabetes and caesarean delivery, and usually only in developed countries (21–23). Other maternal health problems including pregnancy-induced hypertension and post-partum haemorrhage have not been studied in relation to maternal BMI. Estimating adverse birth and maternal health risks associated with underweight, overweight or obesity may help inform decision-making in clinical settings and programme development to improve maternal and child health outcomes.

We undertook a systematic review and pooled available evidence from cohort studies conducted in developing countries with a reference group of normal BMI mothers to determine the association between maternal underweight, overweight or obesity before or during early pregnancy (first trimester or first prenatal visit) and low birthweight, preterm birth, small for gestational age and stillbirth. We assessed the risk of gestational diabetes, pregnancy-induced hypertension, pre-eclampsia, caesarean delivery and post-partum haemorrhage for underweight, overweight and obese mothers relative to normal-weight mothers. In addition, no previous study has estimated the population-attributable risk (PAR) of adverse pregnancy and maternal health outcomes for maternal BMI at pre-pregnancy or during early pregnancy. In order to assess the impact of maternal BMI, we estimated the PAR for selected adverse perinatal and maternal health outcomes by maternal BMI categories.

Methods

The review was undertaken according to the protocol (Supporting Information Text) and Meta-analysis of Observational Studies in Epidemiology (MOOSE) guidelines (Supporting Information Table S1).

Search strategy

We conducted a search for studies on pre-pregnancy and first trimester BMI and risk of perinatal and maternal health outcomes with the assistance of an information specialist. We used four electronic databases: PubMed, Embase, CINAHL and British Nursing Index. We developed search strategies consisting of a combination of free text words, words in titles/abstracts and medical subject headings for exposure, participants and study designs. The full search strategies and search results for the four databases are shown in the Supporting Information Tables S2, S2, S3 and S4. Further searches for eligible studies were conducted by reviewing references within identified papers and relevant journals. We set no language restrictions. We defined low- and middle-income countries based on the World Bank criteria of 2013 (24).

Selection of studies

In the first stage of screening, two assessors (MMR and MSR) independently screened titles and abstracts according to the inclusion and exclusion criteria. In the second stage, four assessors (MMR, SKA, SN and MK) screened the full text of selected studies to assess eligibility. Studies that were cohorts (prospective or retrospective) with pregnant women of reproductive age (15 years or over) were included as subjects. We included studies reporting BMI measures (maternal normal weight, underweight, overweight or obesity), reflecting status preceding any significant pregnancy weight gain (i.e. measured or reported pre-pregnancy and/or during the first trimester or first prenatal visit) and perinatal and maternal health outcomes. We followed the World Health Organization (WHO), Chinese Guidelines for Prevention and Control (GPC) (25) and Institute of Medicine (IOM) (26) definitions for classification of BMI. We treated BMI as our main exposure variable. Height and weight were also separately treated as exposure variables. Therefore, we ignored thresholds for defining maternal BMI in the second screening stage in order to cover studies that reported height or weight only

rather than BMI. Birth and health outcomes were preterm delivery (defined as a birth before 37 weeks of gestation), low birthweight (defined as weight <2,500 g), small for gestational age (defined as birthweight below the 10th percentile of the gestational age and sex), gestational diabetes, pre-eclampsia or pregnancy-induced hypertension, caesarean delivery, including both elective and emergency, and blood loss after delivery. Studies with high-risk populations such as people living with human immunodeficiency virus/acquired immunodeficiency syndrome, malaria, heart disease, diabetes, pre-eclampsia or pregnancy-induced hypertension at baseline were excluded.

Data extraction and management

Prior to tabulating the final data, a data extraction form was designed, trialled and modified. From full-text articles and reports using the agreed form, four review authors (MSR, SKA, SN and MK) independently extracted data on country of origin, year of study, study design, participants, exposures and their time of assessment, outcomes, confounders and measures of association based on information available from publications. We included five articles written in languages other than English (Spanish, Chinese, French and Portuguese) and consulted people proficient in these languages. We excluded two Persian studies due to lack of an appropriate translator with sufficient knowledge on the topic (27,28). We resolved discrepancies through a consensus process. We contacted authors of the original reports about further details when information on outcomes, exposures or study design was unclear.

Quality assessment in included studies

We used a specific checklist to assess the methodological quality of all included cohort studies with the Newcastle-Ottawa Scale criteria set by Wells *et al*. (29). Four authors (MSR, SKA, SN and MK) independently assessed the study quality using a predefined evaluation form for cohort studies, which assigned a score ranging from 0 to 9. Studies were defined as high quality if they scored ≥6, moderate quality if they scored 4–5 or low quality if they scored 0–3.

Statistical analysis

We used BMI categories of normal, underweight, overweight and obese as defined by each study. In the meta-analysis, we used odds ratios (OR) with 95% confidence intervals (CI). If the OR was unavailable, we estimated the unadjusted OR with 95% CI from raw data and then used this estimate in the meta-analysis. A few studies did not include results for normal versus underweight or normal versus obese. In this case, we estimated pooled ORs using random-effects models among those studies reporting an OR for underweight or obese versus normal weight and then replaced this pooled estimation in those studies lacking results for underweight or obese groups. This replacement procedure increases the number of studies and may help to improve the power in meta-analysis. We checked the direction and consistency of ORs before and after imputation. The direction was the same among the studies and pooled estimation remained the same before and after replacing these values, suggesting that the replacement of exposure and outcomes did not have major effects on these findings.

We used fixed-effects (30,31) or random-effects (32) models to estimate summarized results on the basis of heterogeneity (I^2 statistic) assessments. The I^2 value refers to the percentage of variability across studies due to between-study heterogeneity (33). We estimated the I^2 statistic with *P*-values for each meta-analysis to describe the extent of heterogeneity. We used fixed-effects models if $I^2 \leq 50$ and random-effects models for outcomes with heterogeneity measured above this threshold. Values of 25%, 50% and 75% were considered as low, moderate and high heterogeneity, respectively. We used Funnel plots and Egger's regression asymmetry test to examine publication bias (34). To account for these publication biases in meta-analysis, we additionally performed trim-and-fill procedures (35).

We conducted subgroup and random-effects meta-regression analysis to assess the effects of study design (prospective or retrospective), sample size above or below the median value (≤3,715 or >3,715), maternal mean age (≤27 years or >27 years, the median of the sample), BMI measurement point (pre-pregnancy or first trimester), BMI cut-offs (WHO, GPC or IOM), confounding factors (adjusted or unadjusted), country income categories (low- and lower middle-income or upper middle-income countries) and geographic region (Southeast Asia, Middle East or Central and South America). We also performed sensitivity analyses to evaluate differences in pooled effects after dropping a small number of studies that we defined as highly influential on the basis of the variance and weight estimates from meta-analysis.

We estimated the PAR for perinatal and maternal health outcomes due to maternal underweight, overweight and obesity using the estimates obtained from our meta-analysis. The PAR estimates the fraction of adverse outcomes that would not have occurred if the maternal population was not underweight, overweight or obese during the pre-pregnancy or early pregnancy period. PAR was calculated using a modified Levin's formula for multiple exposure categories, proposed by Hanley (36,37).

The formula for the overall PAR calculation is

$$PAR\,(\%) = \frac{\sum_{k=1}^{K} p_k (OR_k - 1)}{\sum_{k=1}^{K} p_k (OR_k - 1) + 1} \times 100, k = 1, 2, \ldots, K$$

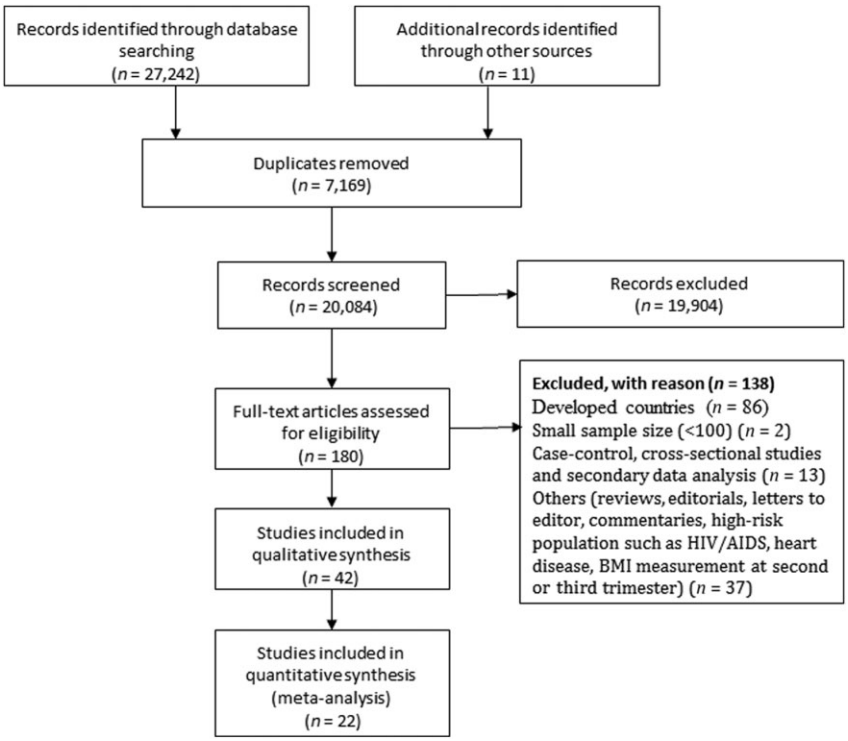

Figure 1 PRISMA flowchart for selection of studies.

while that for the exposure-specific PAR calculation is

$$PAR_K(\%) = \frac{p_k(OR_k - 1)}{\sum_{k=1}^{K} p_k(OR_k - 1) + 1} \times 100, k = 1, 2, \ldots, K$$

Where p is the proportion of exposure to the risk factor in the total population of mothers, OR is the pooled odds ratio of a risk factor for a specific birth or health outcome and K is the number of categories of the risk factor. Prevalence data were used separately for each country and maternal BMI category (underweight, overweight and obesity) to obtain PARs for each group. We used country-specific ORs for low birthweight, preterm birth, small for gestational age, stillbirths, gestational diabetes, pregnancy-induced hypertension, pre-eclampsia, caesarian delivery and post-partum haemorrhage. These were derived from the meta-analysis or from single studies where only one study could be found, while data on the proportion of BMI categories was derived from included population-based studies. We used Stata version 12.1/MP (StataCorp, College Station, TX, USA), for all analyses.

Results

Literature search

We initially identified 27,242 studies, of which 17,322 were from PubMed, 9,252 from Embase, 549 from CINAHL and 119 from the British Nursing Index (Fig. 1). After excluding duplicates, 20,073 remained for title and abstract screening. Of these, 169 full-text papers were reviewed and 138 articles were excluded due to small sample size (<100 women), study design (case-control, cross-sectional or secondary data analysis), non-research material, high-risk populations or BMI measured at second or third trimester (Fig. 1). We also included 11 studies identified through hand search and from reference lists. In total, 42 studies met the inclusion criteria for our review and 22 studies were included in the meta-analysis.

Study characteristics

The basic characteristics of the 42 studies included in our systematic review are presented in Supporting Information Table S6. The majority were conducted in Southeast Asia and in upper middle-income countries (Supporting Information Table S7). There were 34 prospective cohorts and eight retrospective cohorts. Of the 42 studies, 16 reported preterm birth (5,9,10,13–16,38–46), 18 low birthweight (7,10,11,14,15,39,41–45,47–53), seven small for gestational age (9,17,39,41,44,54,55), five stillbirth (9,15,16,44,56), 19 gestational diabetes (5,6,9,12,13,15, 17,38,40,41,43,57–64), nine pregnancy-induced hypertension (5,6,13,17,38,41,63,65,66), nine pre-eclampsia (5,9, 13,15–17,43,60,62), 10 caesarean delivery (6,9,14,15,38, 41–43,60,67), three post-partum haemorrhage (6,9,15) and two perinatal mortality (43,44). The study-specific proportion of BMI and events by perinatal and maternal

Table 1 Meta-analysis summary results

Outcomes	Number of studies	Underweight		Overweight		Obese	
		OR (95% CI)	Heterogeneity (*P*-value)	OR (95% CI)	Heterogeneity (*P*-value)	OR (95% CI)	Heterogeneity (*P*-value)
Pregnancy outcomes							
Preterm birth	11	1.13 (1.01–1.27)	81.2 (<0.001)	1.05 (0.91–1.20)	74.3 (<0.001)	1.21 (0.95–1.53)	79.3 (<0.001)
Low birthweight	8	1.66 (1.50–1.84)	0.0 (0.9)	0.81 (0.73–0.9)	0.0 (0.7)	0.75 (0.65–0.86)	6.5 (0.4)
Small for gestational age	5	1.85 (1.69–2.02)	0.0 (0.4)	0.74 (0.70–0.77)	35.7 (0.2)	0.60 (0.39–0.92)	72.3 (0.01)
Stillbirth	3	0.98 (0.37–2.58)	68.1 (0.04)	1.13 (0.87–1.45)	43.2 (0.2)	1.53 (0.63–3.71)	69.4 (0.1)
Maternal health outcomes							
Gestational diabetes	13	0.47 (0.43–0.52)	0.0 (0.6)	2.18 (1.90–2.51)	54.1 (0.01)	3.74 (2.89–4.84)	78.6 (<0.001)
Pregnancy-induced hypertension	5	0.50 (0.40–0.61)	0.0 (0.5)	2.27 (2.01–2.56)	0.1 (0.4)	5.61 (4.86–6.46)	0.0 (0.5)
Pre-eclampsia	8	0.70 (0.59–0.83)	21.7 (0.2)	1.98 (1.64–2.40)	63.2 (<0.01)	3.87 (3.48–4.29)	42.8 (0.1)
Caesarean delivery	7	0.62 (0.53–0.74)	93.6 (<0.001)	1.32 (1.10–1.58)	84.8 (<0.001)	1.86 (1.36–2.54)	90.4 (<0.001)
Post-partum haemorrhage	3	0.58 (0.49–0.69)	0.0 (0.7)	3.13 (1.00–9.81)	96.9 (<0.001)	3.48 (1.62–7.47)	90.5 (<0.001)

CI, confidence interval; OR, odds ratio.

health outcomes are presented in Supporting Information Tables S8 and S9. Only three of the 42 studies were assessed as moderate in quality, all others were high quality (Supporting Information Table S10).

Pooled estimation of birth and health outcomes

Pooled ORs in the 22 studies included in the meta-analysis are presented in Table 1. Sensitivity analysis, publication bias and trim-and-fill estimates for all outcomes are in Supporting Information Tables S11 and S12. A total of 492,745 (range: 270–353,477) subjects with mean age 27.8 (mean age range: 24.3–32.3) were included in our meta-analysis. In comparison with normal weight, underweight was significantly associated with a greater risk of preterm birth (OR, 1.13; 95% CI, 1.01–1.27), low birthweight (OR, 1.66; 95% CI, 1.50–1.84) and small for gestational age (OR, 1.85; 95% CI, 1.69–2.02; Table 1). Both overweight and obesity were found to be a risk factor for gestational diabetes, pregnancy-induced hypertension, pre-eclampsia, caesarean delivery and post-partum haemorrhage (Table 1). Maternal overweight/obesity was associated with increased risk of stillbirths, but no increasing trend was observed for preterm birth with increasing BMI. Detailed country-specific pooled ORs according to perinatal and maternal health outcomes are presented in Supporting Information Tables S13 and S14. The risk of stillbirth, gestational diabetes, pregnancy-induced hypertension, pre-eclampsia, caesarean delivery and post-partum haemorrhage increased with increasing BMI. Our narrative review results indicated that the risk of delivering babies with low birthweight was significantly higher among underweight (relative risk [RR], 1.30; 95% CI, 1.09–1.54) and shorter (RR, 1.51; 95%, 1.2–1.9) women (Supporting Information Table S15) (47,50). We also found that underweight women were more likely to deliver babies with small for gestational age (Supporting Information Table S15) (5,44). Among obese mothers, incidence of gestational diabetes and caesarean section delivery was higher (Supporting Information Table S15) (38,60).

Stratified analyses

We found moderate to severe heterogeneity in some perinatal and maternal health outcomes (Table 1). Therefore, we conducted stratified analyses to examine the heterogeneity in results for preterm birth, small for gestational age, stillbirth, gestational diabetes, pre-eclampsia, caesarean delivery and post-partum haemorrhage. Stratified analyses by study design, sample size, mean maternal age, BMI measurement timing, BMI cut-offs, confounding factors, country income category and geographic region are presented in Tables 2 and 3 and Supporting Information Tables S16 and S17. Stratifying by geographic region revealed an increased risk in the Middle East among overweight mothers (OR, 1.55; 95% CI, 1.06–2.26; $P = 0.01$) for preterm birth compared with Southeast Asia and Central and South America (Table 2). Obese mothers in the Middle East were more likely to develop pre-eclampsia compared with the other regions, but the association was not statistically significant ($P = 0.20$; Table 3). In general, the BMI thresholds of individual studies were different but there was little evidence that the results varied by BMI cut-off, with preterm birth as the only outcome sensitive to the threshold definition. There was lower risk of preterm birth in the studies using WHO BMI cut-offs among overweight (OR, 0.86; 95% CI, 0.77–0.96; $P = 0.01$) and obese (OR, 0.93; 95% CI, 0.76–1.15; $P = 0.01$) mothers compared with studies that used GPC and IOM cut-offs.

Table 2 Stratified analysis of selected pregnancy outcomes by BMI

Characteristics	Preterm birth		Low birthweight	
	Pooled OR (95%CI)	*P*-value*	Pooled OR (95%CI)	*P*-value*
Underweight				
Study design				
Prospective	1.17 (0.94–1.45)	0.59	1.66 (1.46–1.88)	0.95
Retrospective	1.03 (0.80–1.33)		1.67 (1.40–1.98)	
BMI measurement				
Pre-pregnancy	1.13 (0.87–1.46)	0.12	1.61 (1.39–1.88)	0.63
First trimester	1.07 (1.02–1.13)		1.70 (1.48–1.95)	
BMI cut-off				
WHO	1.27 (0.99–1.63)	0.12	1.59 (1.41–1.79)	0.83
GPC	0.98 (0.85–1.13)		1.73 (1.35–2.22)	
IOM	0.88 (0.54–1.42)		1.67 (0.56–5.00)	
Confounding factors				
Adjusted	1.05 (0.88–1.26)	0.40	1.68 (1.37–2.06)	0.88
Unadjusted	1.18 (0.80–1.74)		1.65 (1.47–1.86)	
Country income category				
Low and lower middle-income	0.71 (0.43–1.18)	0.10	1.67(1.14–2.44)	0.98
Upper middle-income	1.16 (1.03–1.30)		1.66(1.49–1.84)	
Geographic region				
Southeast Asia	1.04 (0.82–1.32)	0.62	1.64 (1.41–1.89)	0.59
Middle East	0.88 (0.54–1.42)		2.46 (1.14–5.31)	
Central and South America	1.25 (0.95–1.65)		1.66 (1.44–1.92)	
Overweight				
Study design				
Prospective	0.83 (0.76–0.90)	0.00	0.81 (0.71–0.91)	0.99
Retrospective	1.15 (1.04–1.27)		0.76 (0.50–1.15)	
BMI measurement				
Pre-pregnancy	1.05 (0.87–1.27)	0.93	0.80 (0.67–0.96)	0.94
First trimester	1.08 (1.01–1.16)		0.80 (0.69–0.93)	
BMI cut-off				
WHO	0.86 (0.77–0.96)	0.01	0.74 (0.61–0.90)	0.46
GPC	1.13 (1.02–1.25)		0.92 (0.72–1.17)	
IOM	1.56 (1.06–2.26)		0.69 (0.22–2.20)	
Confounding factors				
Adjusted	1.09 (0.92–1.29)	0.39	0.83 (0.74–0.95)	0.30
Unadjusted	0.94 (0.74–1.20)		0.74 (0.60–0.90)	
Country income category				
Low and lower middle-income	0.81 (0.67–0.98)	0.15	0.81 (0.71–0.92)	0.91
Upper middle-income	1.09 (0.94–1.26)		0.80 (0.66–0.96)	
Geographic region				
Southeast Asia	1.07 (0.94–1.21)	0.01	0.81 (0.73–0.90)	0.89
Middle East	1.55 (1.06–2.26)		0.69 (0.22–2.20)	
Central and South America	0.83 (0.75–0.91)		0.60 (0.15–2.42)	
Obese				
Study design				
Prospective	0.93 (0.73–1.19)	0.01	0.73 (0.62–0.86)	0.63
Retrospective	1.44 (1.18–1.76)		0.69 (0.32–1.47)	
BMI measurement				
Pre-pregnancy	1.19 (0.89–1.58)	0.79	0.72 (0.52–1.00)	0.99
First trimester	1.28 (0.82–2.02)		0.74 (0.61–0.91)	
BMI cut-off				
WHO	0.93 (0.76–1.15)	0.01	0.67 (0.52–0.86)	0.22
GPC	1.57 (1.36–1.83)		0.96 (0.68–1.35)	
IOM	1.32 (0.74–2.35)		0.36 (0.08–1.65)	
Confounding factors				
Adjusted	1.31 (0.94–1.83)	0.37	0.79 (0.67–0.95)	0.22
Unadjusted	1.06 (0.89–1.26)		0.63 (0.46–0.87)	
Country income category				
Low and lower middle-income	1.10 (0.91–1.33)	0.78	0.73 (0.62–0.87)	0.88
Upper middle-income	1.23 (0.92–1.65)		0.67 (0.41–1.10)	
Geographic region				
Southeast Asia	1.35 (1.10–1.66)	0.02	0.74 (0.62–0.90)	0.53
Middle East	1.32 (0.74–2.35)		0.36 (0.08–1.65)	
Central and South America	0.80 (0.70–0.91)		1.05 (0.29–3.80)	

*Represents the test for significance of the effect modification across strata and these *P*-values come from the meta-regression.

BMI, body mass index; CI, confidence interval; GPC, Guidelines for Prevention and Control for Chinese; IOM, Institute of Medicine; OR, odds ratio; WHO, World Health Organization.

Table 3 Stratified analysis of selected maternal health outcomes by BMI

Characteristics	Gestational diabetes		Pre-eclampsia		Caesarean delivery	
	Pooled OR (95%CI)	*P*-value*	Pooled OR (95%CI)	*P*-value*	Pooled OR (95%CI)	*P*-value*
Underweight						
Study design						
Prospective	0.46 (0.40–0.54)	0.36	0.75 (0.54–1.03)	0.19	0.70 (0.67–0.73)	0.24
Retrospective	0.44 (0.32–0.61)		0.57 (0.40–0.79)		0.55 (0.33–0.92)	
BMI measurement						
Pre-pregnancy	0.48 (0.38–0.59)	0.43	0.66 (0.46–0.96)	0.83	0.70 (0.47–1.03)	0.33
First trimester	0.46 (0.39–0.55)		0.67 (0.52–0.86)		0.58 (0.46–0.72)	
BMI cut-off						
WHO	0.46 (0.37–0.55)	0.18	0.73 (0.55–0.97)	0.43	0.66 (059–0.74)	0.73
GPC	0.54 (0.45–0.64)		0.52 (0.30–0.91)		0.58 (0.28–1.18)	
IOM	0.22 (0.05–0.94)		0.68 (0.36–1.28)		0.41 (0.14–1.26)	
Confounding factors						
Adjusted	0.51 (0.42–0.62)	0.30	0.74 (0.58–0.95)	0.44	0.58 (0.28–1.18)	0.64
Unadjusted	0.46 (0.39–0.54)		0.41 (0.16–1.03)		0.66 (0.59–0.74)	
Country income category						
Low and lower middle-income	0.46 (0.33–0.66)	0.78	NA		0.70 (0.66–0.74)	0.28
Upper middle-income	0.49 (0.43–0.55)		0.68 (0.54–0.85)		0.58 (0.44–0.75)	
Geographic region						
Southeast Asia	0.49 (0.40–0.61)	0.59	0.48 (0.30–0.77)	0.17	0.62 (0.48–0.79)	0.74
Middle East	0.45 (0.36–0.58)		0.68 (0.36–1.28)		0.41 (0.14–1.26)	
Central and South America	0.46 (0.36–0.58)		0.76 (0.63–0.93)		0.70 (0.66–0.74)	
Overweight						
Study design						
Prospective	2.04 (1.68–2.48)	0.33	1.67 (1.41–1.97)	<0.01	1.13 (0.87–1.48)	0.00
Retrospective	2.40 (1.89–3.04)		2.61 (2.13–3.18)		1.55 (1.42–1.68)	
BMI measurement						
Pre-pregnancy	2.18 (1.89–2.51)	0.82	1.84 (1.56–2.17)	0.06	1.30 (0.94–1.80)	0.92
First trimester	2.17 (1.48–3.18)		2.55 (1.43–4.57)		1.38 (1.13–1.68)	
BMI cut-off						
WHO	2.48 (1.87–3.28)	0.37	1.58 (1.32–1.90)	0.17	1.18 (0.93–1.51)	0.18
GPC	1.98 (1.72–2.28)		2.32 (1.68–3.20)		1.60 (1.50–1.69)	
IOM	2.32 (1.35–3.98)		2.38 (1.53–3.70)		1.30 (0.65–2.60)	
Confounding factors						
Adjusted	1.99 (1.82–2.19)	0.44	1.98 (1.46–2.68)	0.92	1.47 (1.24–1.74)	0.30
Unadjusted	2.46 (1.75–3.44)		1.91 (1.69–2.16)		1.25 (0.97–1.61)	
Country income category						
Low and lower middle-income	3.10 (2.11–4.55)	0.13	NA		1.20 (0.77–1.88)	0.15
Upper middle-income	2.11 (1.85–2.41)		1.98 (1.64–2.40)		1.45 (1.28–1.65)	
Geographic region						
Southeast Asia	2.28 (1.88–2.77)	0.75	2.30 (1.78–2.97)	0.04	1.38 (1.14–1.67)	0.44
Middle East	2.22 (1.52–3.25)		2.38 (1.53–3.70)		1.30 (0.66–2.6)	
Central and South America	1.97 (1.59–2.45)		1.51 (1.28–1.78)		0.93 (0.61–1.41)	
Obese						
Study design						
Prospective	3.23 (2.13–4.89)	0.30	3.59 (3.14–4.10)	<0.01	1.49 (0.96–2.32)	0.02
Retrospective	4.37 (2.94–6.49)		5.37 (4.20–6.88)		2.45 (2.21–2.72)	
BMI measurement						
Pre-pregnancy	3.54 (2.65–4.73)	0.63	3.79 (3.24–4.44)	0.04	1.87 (1.14–3.06)	0.97
First trimester	4.16 (2.22–7.79)		5.58 (4.00–7.77)		1.84 (1.11–3.04)	
BMI cut-off						
WHO	3.85 (2.33–6.37)	0.57	3.83 (2.84–5.16)	0.72	1.61 (1.05–2.47)	0.40
GPC	3.26 (2.45–4.32)		4.49 (3.40–5.93)		2.49 (2.24–2.78)	
IOM	6.21(3.21–12.01)		4.70 (2.50–8.83)		1.61 (0.81–3.22)	
Confounding factors						
Adjusted	3.33 (2.46–4.50)	0.31	4.19 (3.21–5.48)	0.88	1.90 (1.24–2.90)	0.92
Unadjusted	4.59 (2.72–7.73)		4.28 (3.05–6.00)		1.84 (1.20–2.81)	
Country income category						
Low and lower middle-income	8.23 (5.26–12.87)	0.03	NA		1.82 (0.82–4.03)	0.82
Upper middle-income	3.42 (2.72–4.30)		4.12 (3.46–4.90)		1.93 (1.44–2.59)	
Geographic region						
Southeast Asia	4.10 (2.92–5.77)	0.53	4.64 (3.63–5.93)	0.20	2.12 (1.52–2.97)	0.19
Middle East	4.04 (1.53–10.67)		4.70 (2.50–8.83)		1.61 (0.81–3.22)	
Central and South America	2.75 (1.94–3.91)		3.25 (2.71–3.89)		0.94 (0.62–1.43)	

*Represents the test for significance of the effect modification across strata and these *P*-values come from the meta-regression.

BMI, body mass index; CI, confidence interval; GPC, Guidelines for Prevention and Control for Chinese; IOM, Institute of Medicine; NA, not applicable; OR, odds ratio; WHO, World Health Organization.

Table 4 Pregnancy and health outcomes attributed maternal body mass index (BMI)

Country	Prevalence, %	Population-attributable risk, %						
		Preterm birth	Low birthweight	Gestational diabetes	Pre-eclampsia	Pregnancy-induced hypertension	Caesarean delivery	Post-partum haemorrhage
Argentina								
Underweight	5.9	2.7			–0.4			
Overweight	19.3	–3.4			8.3			
Obese	8.2	–1.7			13.5			
Total BMI		–2.3			21.5			
Brazil								
Underweight	5.61			–2.0	–1.1	–0.7		
Overweight	25.13			16.5	4.2	15.8		
Obese	17.38			20.0	32.6	41.9		
Total BMI				44.9	35.7	57.0		
China								
Underweight	11.5	0.4	7.9	–4.3	–3.9	–4.6	–2.8	–1.6
Overweight	18.3	1.7	–1.4	13.9	14.1	14.4	9.3	17.1
Obese	6.8	3.7	–0.3	9.9	15.7	19.9	8.6	13.1
Total BMI		5.9	6.2	19.6	25.9	29.7	15.1	28.6
India								
Underweight	20.9		17.5	–5.6		–6.8	–5.2	–2.7
Overweight	20.9		–3.6	22.0		16.0	9.3	55.2
Obese	9.3		–2.1	33.5		25.4	13.7	17.0
Total BMI			11.9	49.9		34.6	17.7	69.6
Iran								
Underweight	15.8	–1.9	19.8	–7.5	–4.0	–7.9	–9.6	
Overweight	13.2	6.8	–3.5	13.5	14.4	18.6	4.1	
Obese	3.6	1.1	–2.0	8.3	10.5	15.3	2.3	
Total BMI		6.1	14.4	14.3	20.9	26.0	–3.2	
Thailand								
Underweight	17.7	11.1	9.7	–10.6	–9.9		–9.0	–7.7
Overweight	13.0	0.6	–4.5	26.9	13.5		4.8	5.3
Obese	4.3	0.0	–2.4	14.9	16.2		4.8	3.0
Total BMI		11.7	2.7	31.2	19.8		0.6	0.6
Turkey								
Underweight	1.8			–0.4				
Overweight	50.0			28.5				
Obese	13.6			34.7				
Total BMI				62.9				

Burden of maternal body mass index

The PARs of selected adverse perinatal and maternal health outcomes attributable to maternal BMI are presented by country in Table 4. The PAR for maternal BMI ranged from 14% in Iran to 63% in Turkey for gestational diabetes, 26% in Iran to 57% in Brazil for pregnancy-induced hypertension, 20% in Thailand to 36% in Brazil for pre-eclampsia and 0.6% in Thailand to 70% in India for post-partum haemorrhage. The highest PAR of gestational diabetes for maternal obesity was found in Turkey (35%), followed by India (34%), Brazil (20%) and Thailand (15%). The PAR for maternal underweight also varied across countries, ranging from 8% in China to 20% in Iran for low birthweight. In India, maternal obesity before or during early pregnancy contributed to 25% of pre-eclampsia, 14% of caesarean delivery and 17% of post-partum haemorrhage; whereas maternal underweight contributed to 18% of low-birthweight deliveries.

Discussion

In this systematic review and meta-analysis, we investigated the effect of maternal BMI (underweight, overweight or obese), before or during early pregnancy, on perinatal and maternal health outcomes in low- and middle-income countries. This is the first attempt to assess the proportion of selected adverse perinatal and maternal health outcomes attributable to maternal BMI. Most included cohort studies were high quality. In women who were overweight or obese during pre-pregnancy or early pregnancy, the meta-analysis demonstrated a significantly higher risk of adverse health

outcomes, including gestational diabetes, pregnancy-induced hypertension, pre-eclampsia, caesarean delivery and post-partum haemorrhage. Underweight mothers were found to be at higher risk of delivering preterm, low-birthweight and small-for-gestational-age babies than normal-weight mothers. Sensitivity analyses confirmed a similar association after dropping a small number of highly influential studies. Higher maternal BMI contributed 10% to 35% of adverse maternal health outcomes and underweight contributed 8% to 20% of adverse perinatal outcomes, especially low birth-weight in developing countries.

The most recent Global Burden of Disease data shows that globally almost 38% of adult women aged 20 years or older fell into overweight categories with a BMI between 25 and 30 kg/m^2 in 2013 (2). In developing countries, overweight or obesity is more prevalent among women than men (2); while underweight remains a significant health problem among women (6,9,13,54). Our review data showed that underweight is more prevalent among women pre-pregnancy or during early pregnancy in India (21%) (6), Thailand (18%) (15), Iran (16%) (13) and China (11%) (9). High maternal BMI is common in Turkey (50% of women are overweight and 14% obese) (40) and Brazil (25% of women are overweight and 17% obese) (54). However, some countries, including India (6), China (9), Iran (13) and Thailand (15), are facing problems due to low and high maternal BMI simultaneously. Our study found a greater burden of poor maternal health attributable to obesity in Brazil (20% of gestational diabetes, 33% of pre-eclampsia and 42% of pregnancy-induced hypertension) and India (34% of gestational diabetes, 25% of pregnancy-induced hypertension, 14% of caesarean delivery and 17% of post-partum haemorrhage). Underweight accounted for a major proportion of low birthweight in Iran (20%), India (18%), China (10%) and Thailand (10%). Our study showed that overall the highest contribution of maternal BMI to the burden of gestational diabetes is in Turkey (63%), followed by India (50%), Brazil (45%), Thailand (31%), China (20%) and Iran (14%). Pregnancy-induced hypertension due to maternal BMI is also more prevalent in Brazil (57%) and India (35%) than China (30%) and Iran (26%). Developing countries are facing a double burden of adverse perinatal and maternal health outcomes attributable to maternal BMI.

According to our results, overweight and obesity are associated with significantly higher risk of gestational diabetes, pregnancy-induced hypertension, pre-eclampsia, caesarean delivery and post-partum haemorrhage relative to normal BMI mothers. Previous meta-analyses found a similar association regarding gestational diabetes (68,69) and caesarean delivery (21). However, these previous papers were mainly limited to developed countries and maternal pre-pregnancy BMI. The effect of overweight and obesity on gestational diabetes, pre-eclampsia and caesarean delivery was consistent by maternal age (aged ≤27 years vs. >27 years) and confounding adjustment (adjusted vs. unadjusted) across studies. We did not find greater risk of adverse maternal health outcomes among underweight women, suggesting that the main contribution to greater adverse maternal health outcomes is from overweight and obese mothers.

Our systematic review and meta-analysis indicated that underweight mothers have a higher risk of delivering low-birthweight and small-for-gestational-age babies. This finding is consistent with one meta-analysis (23), but we cannot compare with other meta-analyses due to different categorization of BMI. For instance, previous studies present the results of low birthweight (20) and preterm birth (18,19) among overweight and/or obese women compared with normal-weight women. Although several epidemiological studies indicated that maternal underweight is still a significant problem in developing countries and the leading risk factor for low birthweight (8,15), preterm birth (15,16) and small for gestational age (8,17), none of these previous meta-analyses considered underweight in their analysis. We considered all four BMI categories in our meta-analysis to investigate perinatal and maternal health outcomes in connection with maternal BMI. Our study demonstrated that the risk of stillbirth is relatively higher among overweight and obese mothers but the association was not statistically significant. Two previous meta-analyses found a significantly higher risk of stillbirth among all higher categories of maternal BMI (18,22). The small discrepancy regarding significant association might be due to the lack of more detailed analysis or the limited number of studies reporting stillbirth as an outcome. To date, there are very few epidemiological studies that reported stillbirth in relation to maternal BMI, especially in developing countries, and the extent of the association is still unclear in low-income countries. Assessment of stillbirth outcomes is lacking in many epidemiological studies of perinatal outcomes and is a neglected issue. Even Millennium Development Goal 4 excludes stillbirth as an outcome of progress in perinatal health.

Consistent with previous studies (70–74), maternal height was inversely associated with risk of low birthweight. Ozaltin *et al*. found that maternal height is negatively associated with risk of child mortality, stunting, undernutrition and wasting (72). Although it is not completely understood how maternal height might be associated with adverse birth and health outcomes, several biomechanical, biological or environmental factors may be involved (75–77). Small uterus size and lower blood flow, found in short-statured women, directly imposes physical limitations on the growth of the uterus, placenta and fetus (70,73,74,78–80). This may lead to membrane stretching, vaginal difficulties during labour and increased risk of preterm birth, low birthweight and caesarean delivery.

Chronic maternal energy and micronutrient deficiency during early life are also an important component limiting growth, resulting in retardation and short stature as well as subsequent restricted fetal growth, duration of gestation or other adverse health outcomes especially in developing countries (74,77,78,81–83). Generally, shorter women are more likely to pass a genetic predisposition for small growth on to their fetus (78).

Our study found that high BMI was associated with a larger increase in risk of gestational diabetes, hypertension and caesarian delivery. The exact biological mechanisms by which obesity affects the mode of delivery or development of gestational diabetes are not well understood. Obesity may increase adipocytes or pelvic soft issue even in the absence of disease (84–86). Abundance of adipocytes in obese women has been suggested as a cause of excessive inflammatory responses and pelvic soft tissue could narrow the diameter of the birth canal, influencing both the development of gestational diabetes and caesarean delivery, respectively (84–86). Thus, policymakers in developing nations need to be aware of both maternal height as well as the growing epidemic of overweight and obesity in populations of young women and the tide of increased maternal risks that this epidemic will bring.

This study focused on high quality cohort studies with large sample sizes, including both published and gray literature, and covered foreign language papers. This enabled us to include a large number of high-quality studies, which allowed us to draw strong conclusions. Additionally, we used a comprehensive search strategy, performed extensive quality assessment, followed the checklist of the MOOSE group (87) and examined heterogeneity with stratified analysis in order to investigate the effect of maternal BMI before or in early pregnancy on birth and health outcomes. However, several limitations should be considered. First, although the WHO developed the standard cut-off points for BMI categorization (underweight, <18.50 kg m^{-2}; normal, 18.50–24.99 kg m^{-2}; overweight, ≥25–<30 kg m^{-2} and obese, ≥30 kg m^{-2}), not all studies used this categorization. Different definitions and categorization can lead to variations in ORs even within a single data set. However, in our systematic review, almost all studies used WHO thresholds except studies in China and Iran. Chinese studies mainly used GPC thresholds for overweight (24 kg m^{-2}–<28 kg m^{-2}) and obesity (≥28 kg m^{-2}) in Chinese adults (25) and Iranian studies followed the categorization of BMI from the IOM, American Academy of Pediatrics and American College of Obstetricians and Gynecologists (underweight, <19.8 kg m^{-2}; normal, 19.8–<26 kg m^{-2}; overweight, 26–29 kg m^{-2} and obese, >29 kg m^{-2}) (26). Consistent with other meta-analyses, we summarized the data according to the original studies' definitions and classification of BMI (20,88). This minimizes the variation of BMI cut-off points across studies and allows the definition of specific populations for each country. Additionally, we performed sensitivity analyses for different BMI thresholds for each BMI category and found little evidence that the summary results varied by definition of BMI. Second, our study addressed only findings related to pre-pregnancy or first trimester BMI and excluded studies analysing data related to second or third trimester BMI, gestational weight gain, visceral fat or fat distribution. However, epidemiological studies suggest that maternal pre-pregnancy or early pregnancy BMI is a strong predictor of pregnancy and maternal health outcomes (6,8,9,16). Third, not all studies presented adjusted ORs and adjustment factors varied across studies. We used both crude and adjusted ORs in the same meta-analysis, so the pooled risk estimates may be biased. However, we conducted meta-regression and subgroup analysis by presence or absence of confounder adjustment and did not find any significant differences in pooled ORs. Fourth, out of 22 studies in the meta-analysis, most of the studies were from upper middle-income countries (18 studies) and only four studies were from low- and lower middle-income countries. Therefore, the results may not be generalizable to low-income settings. This uneven distribution of studies suggests a strong need to improve research on maternal health outcomes and risk factors in the poorest countries, particularly using well-designed prospective studies.

In conclusion, maternal overweight and obesity were associated with a significantly higher risk of gestational diabetes, pregnancy-induced hypertension, pre-eclampsia, caesarean delivery and post-partum haemorrhage. Being short or underweight was associated with a significantly higher risk of low birthweight and small for gestational age. Although overweight and obesity were found to be slightly protective against low-birthweight deliveries, small for gestational age and preterm babies in low-income countries, greater adverse maternal health outcomes were found in these groups. Clinicians and policymakers should counsel women pre-pregnancy or in early pregnancy on the adverse threats of height, underweight, overweight and obesity on their own and their infant's health in order to encourage informed women to optimize their BMI before conception. Clinicians need to be aware of the importance of management of weight in pregnancy and the proper identification and management of BMI-related risks during antenatal care. To prevent height-related pregnancy burden, long-term interventions are necessary in order to improve the height of young women before they become pregnant. Public and private organizations in low- and middle-income countries should jointly work together to introduce long-term interventions including adequate calorie/protein or micronutrient supplementation during the pre-pubescent or adolescent period and prevent child marriage. By acting to prevent this epidemic and to minimize the associated risks, policymakers in low- and middle-

income countries can reduce the consequences of the epidemiological transition for pregnant mothers and infants and can ensure that gains in maternal and child health are not reduced during this complex phase of health system transition.

Conflict of interest statement

No conflict of interest was declared.

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MMR in collaboration with KS and EO developed the research protocol. MK, SN, SKA, MSR and MMR extracted the data and assessed studies for quality. MMR performed the analysis and MSR compiled the tables. MMR and SKA wrote the primary draft. MK wrote the methods. VB checked the consistency of the PAR analysis. KS, EO and SG contributed to the intellectual content of the paper and contributed to writing and editing the paper. This study was supported in part by grants from the Japan Ministry of Health, Labour and Welfare (H25-chikyukibo-ippan-007, MOH 26260101) and by the World Health Organization (grant number HQHWA1208014). The funder had no role in the study protocol design, literature search, data extraction, data analysis, interpretation or write up. We are grateful to Miwako Segawa for her help with the electronic search strategies and retrieval of articles. Thank you also to our colleagues for assistance with the interpretation of the foreign language papers: Ralf Moreno (Spanish/Portuguese), Yi Liao (Chinese) and Shiori Otsuki (French). We appreciate Dr. Naoki Kondo for giving us the time to consult with him regarding handling of the missing data.

Supporting information

Additional Supporting Information may be found in the online version of this article, http://dx.doi.org/10.1111/obr.12293

Table S1. Reporting Checklist for Meta-analysis Of Observational Studies in Epidemiology (MOOSE).
Table S2. PubMed for nutritional disorders and pregnancy outcomes (accessed on 2014/02/13).
Table S3. Embase for nutritional disorders and pregnancy outcomes (accessed on 2014/02/13).
Table S4. CINAHL Plus with full text via EBSCO for nutritional disorders and pregnancy outcomes (accessed 2014/02/13; excluding MEDLINE records).
Table S5. British Nursing Index via Proquest for nutritional disorders and pregnancy outcomes (accessed on 2014/02/13).
Table S6. Background information of the included study in systematic review and meta-analysis.
Table S7. Region and country income profiles.
Table S8. Event and prevalence according to body mass index.
Table S9. Event and odds ratio (95% confidence interval) by body mass index categories and outcomes.
Table S10. Newcastle-Ottawa scale assessment of study quality.
Table S11. Sensitivity analysis after dropping highly influential studies.
Table S12. Publication bias and 'Trim and Fill' estimates.
Table S13. Country-specific summary odds ratios of pregnancy outcomes by maternal body mass index categories.
Table S14. Country-specific summary odds ratios of maternal health outcomes by maternal body mass index categories.
Table S15. Overview of cohort studies included in the narrative review.
Table S16. Stratified analysis of pregnancy outcomes by maternal body mass index.
Table S17. Stratified analysis of health outcomes by maternal body mass index.

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The socioeconomic within-gender gap in informal caregiving among middle-aged women: Evidence from a Japanese nationwide survey

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ABSTRACT

Caregiving to older people with needs has been mainly dependent on informal care provision by female caregivers. Compared with the care burden gender gap, the within-gender gap in women's socioeconomic status (SES) has attracted less policy attention. We investigated the association between middle-aged women's SES and the likelihood of being a primary caregiver for elderly informal care, focusing on household income, women's marital status, work status, and educational background under the universal and public system of formal long-term care provision in Japan. We used repeated cross-sectional data from nationally representative household surveys conducted between 2010 and 2013 to obtain a sample of 2399 women aged between 40 and 60 years living in the same household as a care recipient. We conducted multiple logistic regression analysis to obtain odds ratios of being a primary caregiver in the household regressed on women's SES variables, adjusting for the characteristics of care recipients and household composition. The results showed that single women with lower education were likely to be primary caregivers when the care recipients had severe levels of care needs, whereas the association was null in the case of care recipients with milder conditions. The results indicated that women's low education and non-married status were related to a higher likelihood of becoming a primary caregiver of severely disabled elderly for reasons other than lower economic power.

To emancipate socioeconomically vulnerable women from the care burden, a broader set of social, economic, and welfare policies are needed.

1. Introduction

Caregiving to older people with needs has been mainly dependent on informal care provision by female caregivers. A recent meta-analysis of 229 studies reported that 69% of informal caregivers are women, and that there is a gender gap in the number of caretakers and the hours spent caretaking (Pinquart and Sörensen, 2006). This gender-biased burden of caregiving may result from traditional norms about gender roles (Ikegami, 1997; Tokunaga et al., 2015), gender-specific skills for caring (Allen, 1994), or the wage gender gap in the labor market (Heimueller and Inglis, 2006).

To relieve and equalize the burden of care in the household (Pinquart and Sörensen, 2006; Tokunaga et al., 2015), some countries, including Japan, have introduced a long-term care insurance (LTCI) system to provide formal care services with affordable copayment (Ikegami, 1997; Campbell and Ikegami, 2003) that at least partially increases women's participation in the labor market (Shimizutani et al., 2008). However, a gender gap remains, because women in lower income households do not enjoy such benefits.

The within-gender gap in socioeconomic status (SES) has been poorly studied in relation to informal caregiving. Most previous studies focusing on gender disparity in informal care provision have ignored the SES gap for caregivers (Lee et al., 1993; Jenson and Jacobzone, 2000; Kramer and Lambert, 1999; Mathiowetz and Oliker, 2005; Ingersoll-Dayton et al., 1996; Dahlverg et al., 2007; Montgomery, 1992; Hourven et al., 2013). Gender and SES as represented by income, occupation, and educational attainment are conceptually independent (Baxter and Taylor, 2014; Danesh et al., 1999; Dutton et al., 2005; Krieger et al., 1997), but are intertwined in the social stratification of life chances (Krieger, 2014). Women have a greater risk of low income, low educational attainment, and limited opportunities to access resources such as healthcare (Miech et al., 2003; Griffin and Hu, 2015; Greenstein,

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2000; Stevenson and Wolfers, 2009; Stewart et al., 2007; Blundell et al., 2013; Wolf and Soldo, 1994; Benham, 1974).

Therefore, women of low SES may face a greater risk of a biased care burden, because they lack resources to buy formal care, have less social support, and/or their lack of labor force skills leaves them little choice but to remain in the household and provide informal care. Such an intertwined impact of gender and SES on the distribution of informal care burdens deserves policy attention to design welfare programs for fair contribution and compensation of informal care in society. It is important to focus not only on the gender gap, but also on disparity within women. We are not aware of any literature that directly addresses the socioeconomic within-gender gap in informal caregiving among women.

The aim of this study was to examine the association between women's SES and the likelihood of being a primary caregiver for older people in need. We focused particularly on household income, marital status, work status, and educational background among women.

2. Subjects and methods

2.1. Data source

The public insurance system has been the dominant source of formal long-term care (LTC) in Japan since 2000 (Ikegami, 1997). The eligibility of access to formal care is based solely on a functional assessment of the recipient through a standardized protocol, regardless of a household's demographic and SES conditions, and copayment is reduced or exempted for low-income households. We believe that the investigation of the within-gender gap in informal care provision under public LTC provision in Japan will help to identify a gap attributable to women's status in the household, regardless of whether the household can afford LTC.

For this study, we utilized data from the Comprehensive Survey of Living Conditions of the People on Health and Welfare (CSLCP), a nationwide, representative, population-based cross-sectional survey of households that is conducted every 3 years by the Ministry of Health, Labour and Welfare in Japan. We pooled data from the 2010 and 2013 surveys to obtain a sufficient sample size for analysis. We limited the data to 2010 and 2013 because information regarding educational attainment was available only for these survey years. The 2010 survey used a probabilistic sampling of about 5500 sampling area units stratified by 47 prefectures in Japan. All households in the sampled unit were invited to participate in a self-administered questionnaire survey on household sociodemographic conditions and health status, educational status, marital status, and work status of household members. In 2500 randomly selected area units from the original sample, an additional questionnaire was distributed to all households with a member who was officially approved as eligible for public LTC at the time of the survey. Information collected included formal LTC service use, informal caregiving, and functional conditions of care recipients.

These anonymous secondary data have been approved for research use by the appropriate governmental agency, and the need for ethics research committee approval has been waived.

2.2. Subjects and sampling

We needed to define the “population at risk,” or those who could potentially be both an informal caregiver in the household and part of the labor force in the formal labor market. To focus on the within-gender gap, we excluded male subjects from our analysis. We further limited our sample to females aged between 40 and 60 years, because women in this age range are most likely to be involved in personal care (mainly of their elderly parents) but can be still part of the labor force (Kramer and Lambert, 1999; Attias-Donfut et al., 2005; Pavalko and Arits, 1997). We excluded women older than 60 years, the age of public pension eligibility, because they were likely to be retired, and to be involved in caregiving of their elderly spouses/parents regardless of SES.

In 2010, the original survey included 228,864 households and 609,018 subjects from 5510.

sampling units in 47 prefectures in Japan (household response rate = 79.1%). Among those aged ≧65 years, 13% reported they needed any type of care attention/support in their daily activities, and about 70% actually applied to and were approved as eligible for the LTC services. There were 7192 households eligible for the LTC survey, of which 5912 households provided valid responses. Because the survey only collected detailed information of caregivers living in the same household as a care recipient, we limited our analysis to 2980 households in which care recipients cohabited with primary caregivers in the same household, and also excluded cases where a professional home helper was the primary caregiver.

We excluded 59 households in which the caregiver cared simultaneously for more than two care recipients. Consequently, 1103 households containing 1181 women aged 40–60 years of working age were available as a target sample for further analysis. We conducted similar procedures for the 2013 data; we appended the datasets to obtain 2399 female subjects in 2236 households.

2.3. Measurement

2.3.1. Target variable

Our target variable is a dichotomy of being a primary caregiver for the cohabited elderly with care needs, based on the questionnaire asking who is the primary caregiver of the frail elderly in need in the household.

2.3.2. Female family member characteristics

We considered female family members' characteristics, including age (age <50 or ≥50 years), marital status (whether currently married) (Wolf and Soldo, 1994), and health status (any chronic diseases under treatment). Job status (full-time job, part-time job, no job) (Johnson and Lo Sasso, 2004), and educational attainment (“junior or high school degree,” “community college or training graduate,” and “university graduate or above”) were counted as indicators of individual SES.

2.3.3. Care recipient characteristics

We used care recipients' characteristics, such as age, gender, health status and care eligibility level in public LTCI, as indicators of the amount of care required. An eligibility level higher than II indicated those without functional independence, and needing assistance with meals, toileting, bathing, and clothing (Ikegami, 1997; Tokunaga et al., 2015). We divided the functional disability level into severe (Level III, IV, and V) versus mild (Level I and II, and less than Level I).

2.3.4. Household characteristics

The number of household members aged over 18 years living together was included in the analysis, because it should reflect the household capacity for informal care provision. A count of household members under 18 years was also included, because it should reflect conflicting demand for care provision to dependent children in the household. The CSLCP included an independent subsample for income data, but the LTC questionnaire subsample did not provide this information. We therefore had to estimate household income using a set of household variables common to both subsamples. Using the subsample for income data collection, the household income (sum of labor and pension income) of

households with subjects aged ≧65 years was regressed on the adult equivalent for household size, type of public pension, the number and types of household members in paid work, house ownership, monthly household expenditure, the number of people aged ≧65 years in the household, and average prefectural household income. The obtained regression formula was applied to the LTC survey subsample to impute household income. The income was log-transformed for regression analysis and the imputed numbers were then converted back to normal numbers, and adjusted using the consumer price index for each survey year to enable comparisons over time. The imputed household income was further divided by the square root of the number of household members to obtain equivalent household income, and then categorized into quintiles (Tokunaga et al., 2015)."

2.4. Statistical analysis

We compared the demographic, socioeconomic, and health status of women in a primary caregiver role and those not in this role using t tests and chi-square tests as appropriate. We also compared by women's status as primary caregiver the characteristics of cohabiting care-recipients and their households. Then, we conducted multivariable logistic regressions of the status of a primary caregiver as a target variable, regressed on women's SES, and adjusted for care recipient and household characteristics (e.g., care level, gender, chronic disease under treatment, household composition, and equivalent household income). As the likelihood of one being a primary caregivers may be differentially affected by the severity of care need. Therefore, tests for a statistical interaction between care eligibility level of the care recipient and the primary caregiver's characteristics such as education or marital status were conducted by entering an interaction term for the recipient's care eligibility level (mild and severe) and the caregiver's education/marital status in a multivariate regression model. From this, we found a significant interaction of education/marital status, and analysis was stratified by care eligibility level. Statistical significance was set at $p < 0.05$. The results from the multivariate analysis were expressed as odds ratios (OR) with 95% confidence interval (CI).

3. Results

Table 1 shows the characteristics of female members, care recipients, and households by caregiving status. All 982 women not in a primary-caregiving role cohabited with other caregiving family members, most of whom were women older than 60 years or younger than 40 years (not shown in the table). Primary-caregiver women were on average 3 years older than their counterparts ($p < 0.0001$) and more likely to have chronic conditions ($p = 0.0001$). Primary-caregiver women were more likely to have a high school education or lower and to be non-workers. Finally, they were more likely to cohabit with care recipients who were older, female, and with mild care needs. One-quarter of primary-caregiver women belonged to the lowest household income quartile.

Table 2 shows the results of multivariable logistic regression analysis with primary caregiving status as an outcome. Younger age, full-time work status, and married status were significantly related to the status of not being in a primary caregiving role, whereas education was not significantly related to caregiving status (model 1). However, after including an interaction term between education and care recipient care levels, the interaction was significant (log-likelihood ratio test $p = 0.0003$); high school education or lower was significantly related to the likelihood of being a primary caregiver ($p = 0.0001$). Marital status also showed a significant interaction with care eligibility levels (log-likelihood ratio test $p = 0.015$, not shown in the table).

Table 3 shows the results of ad-hoc analysis stratified by care recipient's care eligibility level. In both groups, younger women and those who worked were less likely to be primary caregivers. Substantially different patterns were observed for marital status and educational attainment. In the case of care recipients with mild eligibility levels, marital status and educational attainment were not significantly related to the likelihood of being a primary caregiver. In contrast, when care recipients had severe levels of care needs eligibility, married women were significantly less likely to be a primary caregiver (OR = 0.41, 95% CIs = 0.27–0.64). Women with lower educational attainment showed a significantly greater likelihood of being a primary caregiver (OR = 1.94, 95% CIs = 1.37–2.74 for women with junior or senior high school degrees compared with university graduates).

4. Discussion

To the best of our knowledge, this study is the first to empirically investigate within-gender socioeconomic inequality among women in sharing the care burden of older people in need. We found that younger women and those in work were less likely to be primary caregivers. Lower education and being single were significantly related to the likelihood of being a primary caregiver only when cohabiting care recipients had severe care eligibility levels.

The lower likelihood for younger and working women to be primary caregivers is not surprising, and may not be causal. To maximize household welfare production, a household must decide how to allocate the available human resources to market-based production for earning and household production of consumption (e.g., care for children and older people in need) (Van Houtven et al., 2012; Penrod et al., 1995). Younger women and those in work may tend to join the formal labor market to earn, and their counterpart women in the household may accept the role of caring for family members with needs. As we did not observe any difference in this trend regardless of care recipients' care need levels, these household decisions probably were not dependent on the amount of care burden.

Women with lower education and those who were single were likely to be primary caregivers of care recipients with severe care levels, but these factors were not significantly associated with caring for recipients with mild conditions. Women's higher education and married status were related to higher household income levels, which may have led a greater capacity to purchase formal institutional care for severely disabled care recipients. However, the private market of institutional long-term care is still young in Japan, and care for frail elderly is mainly provided through public sectors under a long-term care insurance scheme, where service eligibility is strictly dependent on the elderly's functional levels and estimated needs of care. Women's lower education and non-married status remained significant after controlling for household's income levels. The results indicate that women's low education and non-married status were related to a higher likelihood of becoming a primary care giver of severely disabled elderly for reasons other than lower economic power.

Being female, low educational attainment, and being single are known to be associated with a lack of power within the household (Penrod et al., 1995; Cunningham, 2001). Women with less education and those who are single will face difficulties in negotiating with other family members (both males and females) who should carry the main burden of care. When the care burden is expected to be heavy, the negotiation and dynamic relationships among women in the household may lead to a serious conflict, and women with less negotiating power may be forced to accept the burden of

Table 1
Characteristics of female family members, care recipients, and households by females' caregiving status; 2010 and 2013.

Characteristic	All(N = 2399)		Women not in a primary caregiving role(N = 982)		Primary-caregiver women(N = 1417)		P value
Caregiver characteristics		%		%		%	
Mean age(years)	51.84 ± 5.35		50.10 ± 5.62		53.06 ± 4.80		<0.0001
With chronic disease	999	(41.6)	364	(37.1)	635	(44.8)	0.0001
Work							
Full-time	917	(38.2)	437	(44.5)	480	(33.9)	
Part-time	1115	(46.5)	450	(45.8)	665	(47.0)	<0.0001
No job	367	(15.3)	95	(9.7)	272	(19.1)	
Marital status							
Married	2108	(87.9)	877	(89.4)	1231	(86.9)	0.072
Final education							
Junior or senior high school graduates	1075	(44.8)	381	(38.8)	694	(48.9)	
Community college or training graduates	811	(33.8)	350	(35.6)	461	(32.5)	<0.0001
University graduates or above	513	(21.4)	251	(25.6)	262	(18.6)	
Care recipient's characteristics							
Age (years)							
Mean ± SD	83.65 ± 6.39						
Gender							
Male	738	(30.7)					
Female	1661	(69.3)					
Chronic disease under treatments							
Yes	834	(77.6)					
Independence level							
Mild	1074	(44.7)					
Severe	1325	(55.3)					
Household characteristics							
Size_adjusted household income							
1 st quintitle(<=3 million of yen)	571	(23.8)					
2 nd quintitle(3–4 million of yen)	565	(23.5)					
3 rd quintitle(4–6 million of yen)	563	(23.5)					
4 th quintitle(6–9 million of yen)	455	(19.0)					
5 th quintitle(>=9 million of yen)	244	(10.2)					

Abbreviations:SD: standard deviation.
Difference between non-primary-caregivers and caregivers; p values from χ^2 (categorical variables) or *t*-test (continuous variables).

Table 2
Characteristics of female family members that predict the primary caregiving status; results of multivariate logistic regression.

Parameter	DF	**Model1**			**Model2**		
		Estimate	SD	Pr > ChiSq	Estimate	SD	Pr > ChiSq
Age(years)							
Age1 (=>40, <50)	1	−0.75	0.12	<0.0001	−0.76	0.12	<0.0001
Age2 (=<50, =<60)	0	(Reference)			(Reference)		
Final education							
Junior or senior high school degree	1	0.36	0.13	0.053	0.65	0.17	0.0001
Community college or training graduates	1	0.19	0.13	0.15	0.25	0.17	0.13
University graduates or above	0	(Reference)			(Reference)		
Marital status							
Married(Yes:1, No:0)	1	−0.51	0.16	0.0012	−0.50	0.16	0.0017
Chronic disease under treatment							
Yes	1	0.12	0.10	0.26	0.11	0.10	0.25
Work							
Full-time	1	−0.92	0.17	<0.0001	−0.92	0.17	<0.0001
Part-time	1	−0.61	0.18	0.0007	−0.60	0.18	0.001
No job	0	(Reference)			(Reference)		
Interaction: Two-way							
Junior or senior high school degree*mild level	1				−0.67	0.27	0.011
Some college*mild level	1				−0.18	0.28	0.52
University graduates or above*mild level	0				(Reference)		
Recipient care level:mild level	1	0.31	0.10	0.0018	0.68	0.22	0.0021
Recipient care level:severe level	0	(Reference)			(Reference)		

Adjusted for annual dummy, recipients' age, care level, gender, chronic disease under treatment, household composition, and equivalent household income. N = 2399, 1417 of whom were primary caregivers.

being a primary caregiver (Conlon et al., 2014).

Educational level is a major determinant of the value of an individual's time in the labor market (Gronau, 1973). Women with less education have a lower market value in the formal labor market, are less likely to be accepted in the labor force, and are more likely to remain in the household. In addition to a gender-

Table 3
Results of multivariate logistic regression analysis stratified by care recipient's care level.

Mild Level			Severe Level		
	Odds ratio	95%CI		Odds ratio	95%CI
Primary caregivers'characteristics			**Primary caregivers'characteristics**		
Age(years)			Age(years)		
Age1 (=>40, <50)	0.61	(0.43–0.86)	Age1 (=>40, <50)	0.41	(0.29–0.56)
Age2 (=<50, =<60)	1.00	(Reference)	Age2 (=<50, =<60)	1.00	(Reference)
Chronic disease under treatment			Chronic disease under treatment		
(Yes:1, No:0)	1.24	(0.87–1.55)	(Yes:1, No:0)	1.04	(0.78–1.37)
Work			Work		
Full-time	0.46	(0.28–0.76)	Full-time	0.36	(0.23–0.55)
Part-time	0.67	(0.40–1.17)	Part-time	0.46	(0.28–0.74)
No job	1.00	(Reference)	No job	1.00	(Reference)
Marital status			Marital status		
Married(Yes:1, No:0)	1.02	(0.65–1.60)	Married(Yes:1, No:0)	0.41	(0.27–0.64)
Educational attainment			Educational attainment		
Junior or senior high school graduates	1.00	(0.67–1.49)	Junior or senior high school graduates	1.94	(1.37–2.74)
Community college or training graduates	1.05	(0.69–1.62)	Community college or training graduates	1.29	(0.92–1.86)
University graduates or above	1.00	(Reference)	University graduates or above	1.00	(Reference)

Adjusted for annual dummy, recipients' age, care level, gender, chronic disease under treatment, household composition, and equivalent household income. Mild level: N = 1074, 692 of whom were primary caregivers. Severe level: N = 1325, 725 of whom were primary caregivers.

biased wage difference, our results strongly suggest that a within-gender difference in educational background leads to a biased allocation of care burden for those with lower educational attainment.

The informal care of frail elderly people in the household is a non-market activity with a shadow price. Some studies estimate that this price is not low (Posnett and Jan, 1996). Our results suggest that the shadow price of informal caregiving is distributed in a biased way to women with less power in the household system, and that the inequality is not fully solved by public provision of formal care to supplement informal caregiving.

Countries such as Germany and South Korea have introduced a cash benefit to financially compensate informal caregivers. Following extended consideration, the Japanese system has not introduced this cash benefit after concluding that it may bind women to the role of informal caregiver in the household (Campbell et al., 2010; Long, 2004). Other countries such as the UK and Australia have prepared legal protection of caregivers, and provided formal care to support them psychologically and financially (Nolan et al., 1996; Arksey, 2002; Victorian Government Department of Human Services (2005); Hervey, 2004; Gilles, 2000). However, the limited opportunities in the labor market and for social participation among socially and economically vulnerable women, who are likely to be bound to informal care in the household, may result in further disadvantages, such as poorer pension eligibility, lack of worker compensation, and deregulation in working hours and other health/safety protection. Thus, policy making for formal and informal care provision should acknowledge the inequality in care burden and the social inequality in health and socioeconomic conditions among women. This would help to reduce injustice through a broader set of social, economic, and health policies by empowering these women.

Although the major strength of this study is the use of nationally representative population-based data with high coverage, we should acknowledge several limitations. First, this was cross-sectional data, so we cannot draw conclusions about causality: a woman with no job might be burdened with informal care or she might resign from her job to become a caregiver. Further research with panel data is needed. Second, caregivers such as daughters-in-law and married daughters have played an important role in informal caregiving arrangements within East Asian traditional norms (Smith et al., 1991; Nishi et al., 2010), which we did not consider in this study because of the lack of relevant data.

5. Conclusion

Using a nationally representative sample of Japanese women of working age in the community, we demonstrated that the burden of informal care for older people in need is distributed unequally to women with lower SES in the household, despite the universally available formal service provision under the public insurance scheme in Japan. These findings suggest that socioeconomic inequality, in addition to gender-related bias, contributes to the disproportional distribution of the care burden to women with low skills, resources, and power. Policy making should acknowledge the need for a broader set of social, economic, and welfare approaches to emancipate socioeconomically vulnerable women from the shadow cost of informal care for older people.

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