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Notat om brug af antibiotika (AMU) og resistens (AMR) i husdyrproduktionen (særligt i svineproduktionen) under danske forhold

Udarbejdet af John Haugegaard, Formand for Den Danske Dyrlægeforenings (DDD) Faggruppe Svin

Anledning: Pågående drøftelser med danske myndigheder om det hensigtsmæssige i at forlange SPC (prodkutresumeer) fulgt til punkt og prikke (Veterinærlægemiddelforordningen 2019/6's artikel 106.1)

Formål: At danske dyrlæger og landmænd fortsat skal kunne fastholde et lavt og ansvarligt antibiotikaforbrug efter devisen "så lidt som muligt, så meget som nødvendigt"

Baggrund

EU-Kommissionen og den danske Fødevarestyrelse fastholder, at SPC skal følges minutiøst, hvilket vil give et forøget AMU. Spørges kommissionen om det faglige belæg for at afvise **kortere** og **lavere** dosering, henviser de til FAO-rapport[1], som klart har det modsatte synspunkt; at netop **mængden, længden** og **hyppigheden** af AMU har betydning for udvikling af AMR.

Den Danske Dyrlægeforenings vurdering af faglige forhold

FAO's rapport kigger på det globale forbrug af AM, og referencen til vækstfremmende (lav dosis) forbrug er beskrivelsen af det, der foregår i lande som USA, Canada, Sydamerika og store dele af de Asiatiske lande, hvor AMU stadig primært drives af vækstfremmende forbrug og antagelig er op til 10 gange så stort som det danske (dette er rigtigt svært at dokumentere, da ingen andre, indtil nu, registrerer forbrug så minutiøst, som vi gør in DK). En rapport udført af en engelsk dyrlæge, hvor forbrug til svin i 6 udvalgte lande er undersøgt i 2018[5] viser dog, at det netop er lande, som fortsat har omfattende brug af vækstfremmere der ligger meget højt (aktuelt Canada og USA). Det er primært disse lande og denne karakter af brug af AM, FAO henviser til. Tilsvarende kan man i ESVAC rapporten[6] se, at det totale forbrug (ikke opgjort per dyreart pga manglende data uden for DK) er markant højere i en række europæiske lande. Det er ESVAC rapporten, der får EU-kommissionen til at rette fokus på 50 % reduktion, som beskrevet i Farm to Fork strategien. ESVAC rapporten er vanskelig at bruge til at sige noget éntydigt om svineproduktionens forbrug, idet lande med meget stor produktion af lam og fisk (hhv fx UK og Norge) vil have et lavt gennemsnitligt forbrug per produceret kg kød (mg/PCU), hvilket ikke nødvendigvis afspejler forholdene i fx svineproduktionen.
Enhver, der har rejst på studieture i europæisk svineproduktion i lande fra Belgien og sydpå – og for den sags skyld også i UK - vil vide, at det terapeutiske forbrug er meget stort, set med danske øjne. Det er ikke ualmindeligt med 3-4 ugers behandlinger oralt med AM, som måske gentages 2-3 gange gennem en gris' liv. Det er den type behandling EU-kommissionen – med

god grund – henviser til i Farm to Fork strategipapiret og ønsker begrænset. Ikke den begrænsede behandling, vi har under danske forhold og som holdes lavt bl.a. pga. vores Gult Kort ordning og - ikke mindst - pga. et ønske, hos både dyrlæger og landmænd, om at begrænse risikoen for at udvikle AMR.

Belæg for at følge SPC

Der findes ikke videnskabeligt belæg for at følge SPC! SPC er udarbejdet af kommercielle virksomheder, som har truffet et valg om hvilken behandlingsstrategi de ville anbefale. En kommerciel logik vil tilsige "jo mere, jo bedre". Den dokumentation som fremlægges viser, at i den givne dosis og den givne behandlingslængde virker produktet mod de lidelser/smitstoffer, som det er registreret imod.
Men der er **intet** i de undersøgelser, som har afsøgt den nedre grænse for hvor meget der kan bruges. Der findes altså ikke videnskabeligt belæg for, at påstå at en given behandling ikke kan seponeres før tid, blot fordi et produkt er godkendt med en bestemt behandlingslængde eller dosis. Llewelyn et al.[3] fremhæver at den gamle opfattelse, at "man skal behandle færdig" snarere udelukkende har anekdotisk belæg, som går helt tilbage til Flemings opdagelse af penicillinen og som bare ukritisk har fulgt lægevidenskaben og ukritisk er adapteret også af veterinærvidenskaben.

Belæg for reduceret forbrug

Kigger vi derimod efter belæg for at kunne reducere forbruget ift. SPC, findes der humant en hel del videnskabelig evidens for, at dette kan lade sig gøre. Dette er refereret af Llewelyn[3]. Ydermere viser Sande-Bruisma et al.[2], at der, humant, er en konsistent sammenhæng mellem resistens hos udvalgte patogener isoleret blandt europæiske landes indbyggere og de respektive landes totale forbrug af AM.
En dansk undersøgelse fra 2020[4] sætter tyk streg under opfattelsen, at "jo mindre, jo bedre" gælder. Denne artikel undersøger 50 svinebesætningers totale AMU og sætter det i forhold til samme besætningers AMR i tarmbakterierne på slagtetidspunktet. Der er en lineær sammenhæng mellem udviklingen af resistensgener og AMU. Denne artikel virker til at være en dansk nøgleartikel og kan evt. inddrages i fastlæggelse af faktorer i det differentierede gule kort fremadrettet.

Konklusion

DDD er stærkt bekymrede for den blinde efterlevelse af artikel 106.1, som vi oplever at EU-kommissionen og de danske myndigheder presser os til. Det er vi, fordi denne efterlevelse vil tvinge os til at bruge mere af især den orale antibiotika og, som de danske undersøgelser klart viser, dermed øge forekomsten af resistensgener i den danske grisepopulation.

Anmodning

DDD vil på det kraftigste anmode EU-kommissionen, Fødevarestyrelsen og danske beslutningstagere om at omgøre denne beslutning, da den direkte vil modarbejde den store indsats, som danske landmænd og dyrlæger i svineproduktionen har gjort for at reducere forbruget siden vi i slutningen af 90'erne afviklede brugen af antibiotiske vækstfremmere.

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Referencer

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Tekst og grafer af særlig interesse er nedenfor klippet ud af ovennævnte artikler. Bilag nummer referere til reference nummer.

Bilag 1

Citat fra FAO (fremhævelser af red.):

*The rate of AMR emergence in ecosystems such as the human or animal gut is likely to be highly dependent on the **quantity** of antimicrobials used, along with the **duration and frequency** of exposure. In animal production, the **prolonged use of antimicrobial growth promoters (AGPs)** at subtherapeutic levels in large groups of livestock is known to encourage resistance emergence and is still common practice in many countries today.*

https://www.fao.org/3/i6209e/i6209e.pdf

EXECUTIVE SUMMARY

It is now accepted that increased antimicrobial resistance (AMR) in bacteria affecting humans and animals in recent decades is primarily influenced by an increase in usage of antimicrobials for a variety of purposes, including therapeutic and non-therapeutic uses in animal production. Antimicrobial resistance is an ancient and naturally occurring phenomenon in bacteria. But the use of antimicrobial drugs – in health care, agriculture or industrial settings – exerts a selection pressure which can favour the survival of resistant strains (or genes) over susceptible ones, leading to a relative increase in resistant bacteria within microbial communities. It has been observed that, in countries where use of particular substances (e.g. fluoroquinolones) is banned in animal production, there are low levels of resistance to these antimicrobials in livestock populations. The rate of AMR emergence in ecosystems such as the human or animal gut is likely to be highly dependent on the quantity of antimicrobials used, along with the duration and frequency of exposure. In animal production, the prolonged use of antimicrobial growth promoters (AGPs) at subtherapeutic levels in large groups of livestock is known to encourage resistance emergence, and is still common practice in many countries today. Due to the interdependence and interconnectedness of epidemiological pathways between humans, animals and the environment, determining the relative importance of factors influencing AMR emergence and spread in animal production is a significant challenge, and is likely to remain one for some time.

In intensive livestock production systems, resistant bacteria can spread easily between animals and this can be exacerbated if biosecurity is inadequate. While some studies have shown reduced levels of AMR on organic farms, a high prevalence of multidrug-resistant (MDR) *Campylobacter* strains has been detected in organic pig farms in the United States even in the absence of antimicrobial usage (AMU).

In aquaculture, AMR can develop in aquatic and fish gut bacteria as a result of antimicrobial therapy or contamination of the aquatic environment with human or animal waste. The extent and persistence of antimicrobial residues in aquatic systems is unknown and current evidence is conflicting. Furthermore, no international guidelines currently exist for maximum antimicrobial residue limits in water. Water is an important vehicle for the spread of both antimicrobial residues and resistance determinants, since contaminated water can be consumed directly by humans and livestock and used to irrigate crops.

Food is likely to be quantitatively the most important potential transmission pathway from livestock to humans, although direct evidence linking AMR emergence in humans to food consumption is lacking. There is a theoretical risk of widespread dissemination of AMR due to the increasingly global nature of food trade and human travel. This would mean that strains of resistant bacteria could now very quickly reach parts of the world where they had previously not been present. Agricultural systems in emerging economies such as China and India have changed radically in recent years, becoming increasingly intensive in order to meet growing domestic and global demands for animal protein. This is likely to heighten the occurrence and spread of infectious diseases in these systems, thereby leading to increased AMU and therefore resistance.

If the selection pressure resulting from AMU in animals and humans were to be removed, this would still not completely halt the emergence and global spread of AMR due to the ability of AMR genes to move between bacteria, hosts and environments, and the occurrence of spontaneous mutations.

However, the release of large quantities of antimicrobials or resistant bacteria into the environment is still thought to be an important point for control, and therefore measures which encourage the prudent use of antimicrobials are likely to be extremely useful in reducing the emergence and spread of AMR. Future development of quickly biodegradable antimicrobials could help to reduce environmental contamination, and pharmacodynamic studies in livestock can be used to inform the optimization of AMU. Improved hygiene and biosecurity should be a major focus for all types of animal production systems so that the risks of introducing pathogens and resistance genes – and the spread of these within animal populations – can be reduced. Detailed, specific recommendations for countries to move towards more prudent AMU in different agricultural settings are, however, beyond the scope of this paper.

An improved understanding of the epidemiology of AMR emergence and spread in animal production will provide an essential foundation for successful mitigation strategies. There are still considerable gaps in our understanding of the complex mechanisms that lead to the emergence of AMR in bacteria, and the interactions that take place within microbial ecosystems enabling the transfer of resistance between bacteria. There are insufficient data at present to determine quantitatively how important the selection pressure of AMU is for the emergence of AMR in bacteria. Evidence regarding AMR transmission pathways between food animals and humans is lacking, especially from low- and middle-income countries (LMICs).

Such pathways are likely to be highly complex and multi-directional, especially in LMICs, but are still largely unknown. There remains little doubt, however, that the most significant factor in AMR emergence in humans is AMU for human treatment and prevention. It is clear that both human and animal AMU can contribute to environmental contamination, although collection of meaningful data is challenging. The relationships between different types of farming systems and both AMU and the emergence and spread of AMR are discussed in this paper, including extensive and organic systems, but there is still a notable lack of knowledge on the role that sustainable agriculture systems can play in combatting AMR. Most importantly, future research needs to involve an interdisciplinary (e.g. One Health) approach, integrating agricultural, medical, environmental and social sciences, and especially recognizing the importance of human behaviour. A set of specific recommendations to fill current knowledge gaps is presented in the final section of this technical paper.

B

Bilag 2

RESEARCH

Antimicrobial Drug Use and Resistance in Europe

Nienke van de Sande-Bruinsma, Hajo Grundmann, Didier Verloo, Edine Tiemersma, Jos Monen, Herman Goossens, Matus Ferech, and the European Antimicrobial Resistance Surveillance System and European Surveillance of Antimicrobial Consumption Project Groups[1]

CME ACTIVITY

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Learning Objectives

Upon completion of this activity, participants will be able to:

- Identify the classes of antimicrobial drugs most commonly used in Europe.
- Describe patterns of antimicrobial drug use across regions in Europe.
- Identify the most widely used antimicrobial drugs by country in Europe.
- List European countries that show the highest antimicrobial drug resistance proportions.
- Describe the association between antimicrobial drug use and the emergence of resistance.

Editor

Anne Mather, Technical Writer-Editor, *Emerging Infectious Diseases. Disclosure: Anne Mather has disclosed no relevant financial relationships.*

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Disclosures: ***Nienke van de Sande-Bruinsma, MSc, PhD; Hajo Grundmann, MD, PhD; Didier Verloo, DVM; Edine Tiemersma, PhD; Jos Monen, MSc; Herman Goossens, MD, PhD;*** *and* ***Matus Ferech, MSc, PhD,*** *have disclosed no relevant financial relationships.*

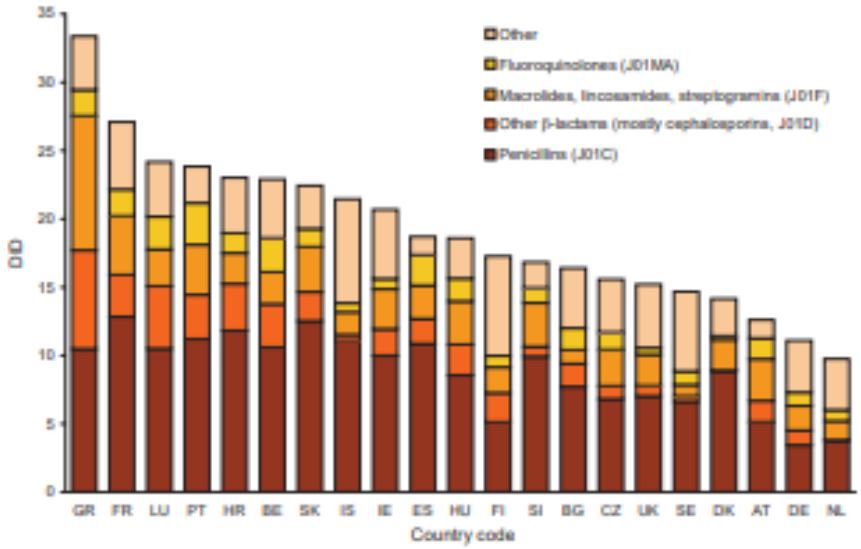

Figure 1. Total antimicrobial drug consumption in ambulatory care in defined daily doses per 1,000 inhabitants per day (DID) by antimicrobial class in 21 European countries in 2004. See Table 1 footnote for country designations.

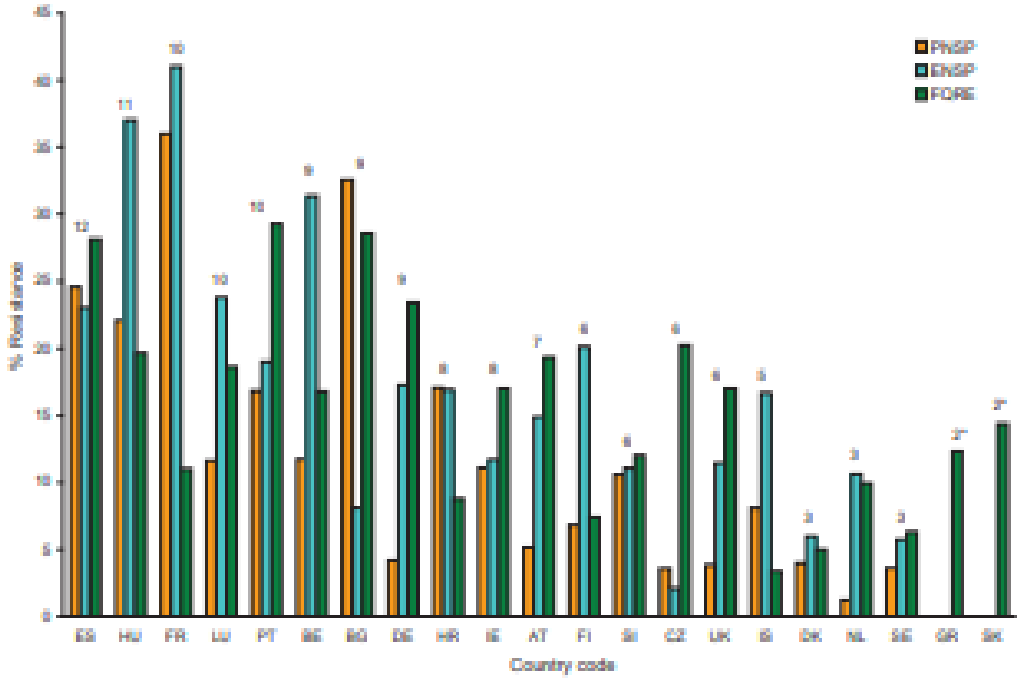

Figure 2. Proportion of penicillin-nonsusceptible *Streptococcus pneumoniae* (PNSP), erythromycin-nonsusceptible *S. pneumoniae* (ENSP), and fluoroquinolone-resistant *Escherichia coli* (FQRE) in 2005, ranked in descending order by country-specific resistance score indicated above bars. *For Greece and Slovakia, data on *S. pneumoniae* resistance were not available. Country (total no. of *S. pneumoniae* isolates reported/ total no. of *E. coli* isolates reported): ES (740/2993); HU (86/468); FR (632/6028); LU (43/188); PT (202/1086); BE (1539/1461); BG (43/196); DE (119/957); HR (129/637); IE (397/1411); AT (290/2049); FI (525/1743); SI (208/657); CZ (194/2233); UK (1373/2359); IS (37/117); DK (1081/1283); NL (802/2140); SE (1017/3035); GR (0/1136); SK (0/132). See Table 1 footnote for country designations.

Bilag 3

BMJ 2017;358:j3418 doi: 10.1136/bmj.j3418 (Published 2017 July 26)

ANALYSIS

The antibiotic course has had its day

With little evidence that failing to complete a prescribed antibiotic course contributes to antibiotic resistance, it's time for policy makers, educators, and doctors to drop this message, argue **Martin Llewelyn and colleagues**

Martin J Llewelyn *professor of infectious diseases*[1 2], Jennifer M Fitzpatrick *specialist registrar in infection*[2], Elizabeth Darwin *project manager*[3], SarahTonkin-Crine *health psychologist*[4], Cliff Gorton *retired building surveyor*[5], John Paul *consultant in microbiology*[6], Tim E A Peto *professor of infectious diseases*[7], Lucy Yardley *professor of health psychology*[8], Susan Hopkins *consultant in infectious diseases and microbiology*[9], Ann Sarah Walker *professor of medical statistics and epidemiology*[3]

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Table

Table 1| **Indications for which duration of antibiotic treatment has been evaluated by randomised controlled trial**

Indication	No of days treatment		Main evidence	Evidence on resistance
	Standard	Evaluated		
Otitis media[19]	10	5	Clinical failure higher with 5 days than 10 days treatment (1 trial)	Similar short term selection of resistance in nasopharyngeal organisms
Streptococcal pharyngitis[20]	10	3-6	Comparable effect of 3-6 days oral antibiotics to 10 days penicillin in children with streptococcal throat infection (Cochrane review of 20 studies)	Not assessed
Community acquired pneumonia[21]	7-10	5	Non-inferiority of 5 day course once afebrile and clinical stability improving compared with physician guided therapy (median 10 days) for clinical success (1 trial)	Not assessed. β-lactam treatment >5 days associated with greater carriage of resistant *S pneumoniae*
Cellulitis[22]	7-14	5	Non-inferiority of 5 day course compared with 10 days for clinical resolution (1 trial)	Not assessed
Pyelonephritis[23 24]	14	5-7	Non-inferiority of 7 *v* 14 days ciprofloxacin for cure[12] and 5 days levofloxacin *v* 10 days ciprofloxacin for eradication of infection and clinical cure[13]	Not assessed
Nosocomial pneumonia[25 26]	10-15	7-8	Non-inferiority of short course treatment of suspected pneumonia among critical care patients on ICU mortality and infection recurrence (multiple trials)	Lower risk of further or resistant infection in patients receiving shorter duration therapy
Intra-abdominal sepsis[27]	7-14	4	Non-inferiority of fixed 4 day course compared with physician guided therapy (median 8 days) for surgical site infection, recurrent intraabdominal infection, or death (1 trial)	Non-significantly lower rates of extra-abdominal resistant infection in short course group

Bilag 4

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Predicting effects of changed antimicrobial usage on the abundance of antimicrobial resistance genes in finisher' gut microbiomes

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ABSTRACT

It is accepted that usage of antimicrobials (AMs) in food animals causes the emergence and spread of antimicrobial resistance (AMR) in this sector, while also contributing to the burden of AMR in humans. Curbing the increasing occurrence of AMR in food animals requires in-depth knowledge of the quantitative relationship between antimicrobial usage (AMU) and AMR to achieve desired resistance reductions from interventions targeting AMU. In the observational study, the relationships between lifetime AMU in 83 finisher batches from Danish farms and the AMR gene abundances of seven antimicrobial classes in their gut microbiomes were quantified using multi-variable linear regression models. These relationships and the national lifetime AMU in pigs were included in the predictive modelling that allowed for testing of scenarios with changed lifetime AMU for finishers produced in Denmark in 2014. A total of 50 farms from the observational study were included in validating the observational study and the predictive modelling. The results from the observational study showed that the relationship was linear, and that the parenteral usage of AMs had a high effect on specific AM-classes of resistance, whereas the peroral usage had a lower but broader effect on several classes. Three different scenarios of changed lifetime AMU were simulated in the predictive modelling. When all tetracycline usage ceased, the predicted interval reductions of aminoglycoside, lincosamide and tetracycline resistance were 4–42 %, 0–8 % and 9–18 %, respectively. When the peroral tetracycline usage of the 10 % highest users was replaced with peroral macrolide usage, the tetracycline resistance fell by 1–2 % and the macrolide and MLSb resistance increased by 5–8 %. When all extended-spectrum penicillin usage was replaced with parenteral lincosamide usage, the beta-lactam resistance fell by 2–7 %, but the lincosamide usage and resistance increased by 194 % and 10–45 %, respectively. The external validation provided results within the 95 % CI of the predictive modelling outcome at national level, while the external validation at farm level was less accurate. In conclusion, interventions targeting AMU will reduce AMR abundance, though differently depending on the targeted AM-class and provided the reduction of one AM-class usage is not replaced with usage of another AM-class. Predicting several classes of AMR gene abundance simultaneously will support stakeholders when deciding on interventions targeting AMU in the finisher production to avoid adverse and unforeseen effects on the AMR abundance. This study provides a sound predictive modelling framework for further development, including the dynamics of AMU on AMR in finishers at national level.

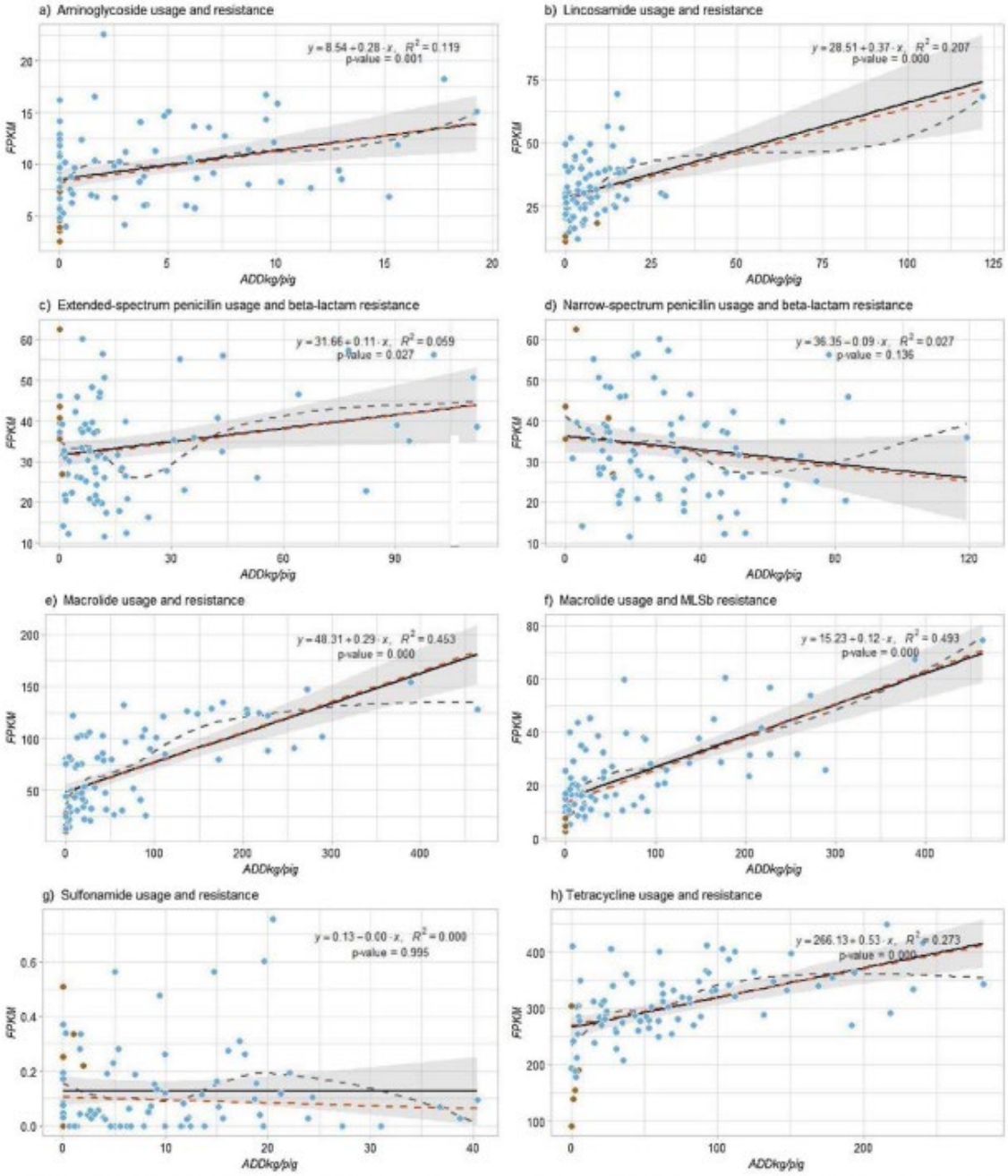

Fig. 1. Plotted observations of lifetime AMU (*ADDkg/pig*) against resistance gene abundance (*FPKM*) of conventional (blue) and organic farms (brown) of the observational study. In addition, the three regressions of *FPKM* as a function of *ADDkg/pig*; i) LOESS local (dotted grey line), ii) linear with 95 % confidence interval (CI) (black line and grey area), and bi-square robust (orange dotted line) together with the function, p-value and R^2 value are shown in each plot (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article).

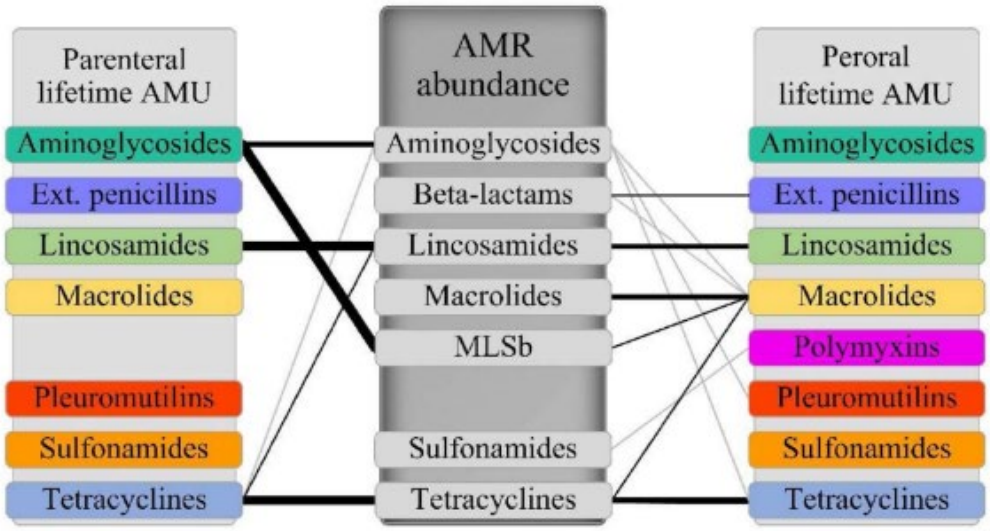

Fig. 2. Multi-variable regression models of the effects of parenteral and peroral lifetime AMUs on seven classes of AMR gene abundances of the observational study. Black lines indicate the main significant result, and thickness is proportional to the relative size of the β-coefficient. Grey lines indicate significant result with β-coefficient less than 0.05.

Bilag 5

Detaljeret studie af **svineproduktionens** forbrug i udvalgte lande (ADHB studie fra Nuffield universitet, UK 2018, Georgina Crayford)

Table 1: Pig production figures and antibiotic use levels in the countries visited during the Scholarship

	National breeding herd	Annual pig slaughterings	Antibiotic use (mg/kg)	Notes on antibiotic use figure
UK	409,000[i]	9,110,000[ii]	131 (pigs)	On-farm antibiotic use figure for 2017, collected into the industry's electronic medicine book (eMB)[iii]
Finland	116,000[iv]	2,145,000[v]	18.6 (all livestock)	2016 antibiotic sales figure for all livestock [vi]
Sweden	141,000[iv]	2,551,000[v]	12.7 (pigs)	2016 antibiotic sales figure for pigs [vii]
Denmark	1,237,000[iv]	19,108,000[v]	44.3 (pigs)	Estimation calculated using reported tonnage used in pigs in 2016[viii]
USA	6,200,000[ix]	118,219,800[x]	380 (pigs)	Estimation for Smithfield Foods pork supply chain based on antibiotic use figure for 2016 [xi]
Canada	1,253,000[xii]	21,424,000[xiii]	400 (pigs)	Estimation based on a pilot project involving 40 pig farms in Ontario
Australia	267,000[xiv]	4,850,000[xiv]	?	No (recent) data available for sales or usage of antibiotics in livestock

Bilag 6

ESVAC rapport for 2020, der viser alle dyrearters forbrug (i mangel af landespecifikke data) – offentliggjort november 2021.

Table 4. Sales, in tonnes of active substance, of antimicrobial VMPs marketed mainly for food-producing animals[1], PCU and sales in mg/PCU, by country, in 2020

Country	Sales (tonnes) for food-producing animals	PCU (1,000 tonnes)	mg/PCU
Austria	43.7	942.3	46.3
Belgium	180.4	1,745.3	103.4
Bulgaria	61.1	368.4	166.0
Croatia	22.6	328.9	68.6
Cyprus	48.3	122.6	393.9
Czechia	39.3	699.3	56.3
Denmark	88.7	2,384.7	37.2
Estonia	5.7	115.9	49.2
Finland	8.0	494.4	16.2
France	394.4	6,964.9	56.6
Germany	684.6	8,172.8	83.8
Greece	108.4	1,216.5	89.1
Hungary	136.1	801.0	169.9
Iceland	0.5	135.3	3.8
Ireland	102.9	2,189.8	47.0
Italy	689.3	3,790.4	181.8
Latvia	4.8	157.6	30.8
Lithuania	6.2	302.6	20.5
Luxembourg	1.6	54.4	29.0
Malta	1.7	14.7	116.1
Netherlands	156.4	3,114.9	50.2
Norway	4.7	2,030.8	2.3
Poland	853.2	4,541.7	187.9
Portugal	177.9	1,012.0	175.8
Romania	173.7	3,003.7	57.8
Slovakia	11.8	228.3	51.9
Slovenia	5.9	176.0	33.3
Spain	1,244.5	8,067.5	154.3
Sweden	8.7	786.0	11.1
Switzerland	27.7	806.1	34.3
United Kingdom	214.4	7,115.2	30.1
Total 31 countries	**5,507.4**	**61,884.2**	**89.00***

[1] Tablets are excluded as they are used almost solely in companion animals; injectable antimicrobial VMPs can also be used in companion animals; a few other products may solely be used in companion animals, but as their proportional use is minor, these are included in the sales for food-producing animals.

* Total mg/PCU for 31 countries represents aggregated sales (tonnes) for food-producing animals, including horses and farmed fish, normalised by the aggregated PCU (1,000 tonnes).